

IMPAX LABORATORIES INC

FORM 10-Q (Quarterly Report)

Filed 07/25/02 for the Period Ending 06/30/02

Address	30831 HUNTWOOD AVENUE HAYWARD, CA 94544
Telephone	510-240-6000
CIK	0001003642
Symbol	IPXL
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

IMPAX LABORATORIES INC

FORM 10-Q (Quarterly Report)

Filed 7/25/2002 For Period Ending 6/30/2002

Address	30831 HAYWARD AVE HAYWARD, California 94544
Telephone	215-289-2220
CIK	0001003642
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

U.S. Securities and Exchange Commission

Washington, D.C. 20549

Form 10Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2002

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number 0-27354

Impax Laboratories, Inc.

(Exact name of registrant as specified in its charter)

Delaware

65-0403311

(State or other jurisdiction of
incorporation or organization)

(I.R.S. Employer
Identification No.)

30831 Huntwood Avenue - Hayward, California

94544

(Address of principal executive offices)

(Zip code)

Registrant's telephone number including area code (215) 289-2220

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days.

Yes X No

The number of shares outstanding of the registrant's common stock as of July 22, 2002 was approximately 47,759,581.

IMPAX LABORATORIES, INC.

INDEX TO FORM 10-Q

FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2002

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PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

**IMPAX LABORATORIES, INC.
BALANCE SHEETS**
(unaudited)

(in thousands, except share and per share data)

	June 30, 2002 -----	December 31, 2001 -----
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 20,486	\$ 15,044
Short-term investments	7,914	20,422
Accounts receivable, net	4,561	3,523
Inventory	4,688	3,488
Prepaid expenses and other assets	1,447	1,506
	-----	-----
Total current assets	39,096	43,983
Property, plant and equipment, net	31,398	24,334
Investments and other assets	578	574
Goodwill, net	27,574	27,574
Intangibles, net	955	1,147
	-----	-----
Total assets	\$ 99,601	\$ 97,612
	=====	=====
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Current portion of long-term debt	\$ 232	\$ 232
Accounts payable	4,304	3,996
Accrued expenses	4,977	3,575
Deferred revenues - current	66	0
	-----	-----
Total current liabilities	9,579	7,803
Refundable deposit	23,752	22,876
Long-term debt	6,752	6,868
Deferred revenues	2,684	117
	-----	-----
	42,767	37,664
	-----	-----
Mandatorily redeemable convertible Preferred Stock:		
Series 2 mandatorily redeemable convertible Preferred Stock, \$0.01 par value 75,000 shares outstanding at June 30, 2002, and December 31, 2001, redeemable at \$100 per share	7,500	7,500
	-----	-----
	7,500	7,500
	-----	-----
Stockholders' equity:		
Redeemable convertible Preferred Stock	--	--
Common stock, \$0.01 par value, 75,000,000 shares authorized and 47,750,632 and 46,680,047 shares issued and outstanding at June 30, 2002, and December 31, 2001, respectively	477	466
Additional paid-in capital	131,015	122,957
Unearned compensation	(497)	(673)
Accumulated deficit	(81,661)	(70,302)
	-----	-----
Total stockholders' equity	49,334	52,448
	-----	-----
Total liabilities and stockholders' equity	\$ 99,601	\$ 97,612
	=====	=====

The accompanying notes are an integral part of these financial statements.

IMPAX LABORATORIES, INC.
STATEMENTS OF OPERATIONS
(unaudited)

(dollars in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2002	2001	2002	2001
Net sales	\$ 5,145	\$ 1,136	\$ 8,577	\$ 2,908
Cost of sales	3,982	1,992	7,121	4,268
Gross margin (loss)	1,163	(856)	1,456	(1,360)
Research and development	4,476	2,415	7,366	5,010
Less: Teva reimbursements	(138)	--	(304)	--
Research and development, net	4,338	2,415	7,062	5,010
Selling	646	806	1,304	1,123
General and administrative*	1,939	2,236	4,109	4,395
Other operating income (expense), net	21	39	(9)	64
Net loss from operations	(5,739)	(6,274)	(11,028)	(11,824)
Interest income	167	161	402	423
Interest expense**	(366)	(37)	(733)	(87)
Net loss	\$(5,938)	(6,150)	\$(11,359)	\$(11,488)
Net loss per share (basic and diluted)	\$ (0.13)	\$ (0.15)	\$ (0.24)	\$ (0.31)
Weighted average common shares outstanding	47,306,741	41,138,673	47,061,223	37,565,128

* Includes amortization of goodwill of \$876,000 in the quarter ended June 30, 2001 and \$1,752,000 in the six months ended June 30, 2001. There was no amortization of goodwill in 2002.

** The total interest expense of \$366K for the quarter ended June 30, 2002, which was reduced by \$222K in capitalized interest, included interest of \$438K on the refundable deposit from TEVA. The total interest of \$733K for the six months ended June 30, 2002, which was reduced by \$394K in capitalized interest, included interest of \$876K on the refundable deposit from TEVA.

The accompanying notes are an integral part of these financial statements.

IMPAX LABORATORIES, INC.
STATEMENTS OF CASH FLOWS
(unaudited)

(dollars in thousands)

	Six Months Ended June 30,	
	2002	2001
	-----	-----
Cash flows from operating activities:		
Net loss	\$(11,359)	\$(11,488)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation and amortization	1,032	3,057
Non-cash compensation charge (warrants and options)	176	260
Change in assets and liabilities:		
Accounts receivable	(1,038)	(964)
Inventory	(1,200)	74
Prepaid expenses and other assets	55	(314)
Accounts payable and other liabilities	4,083	(75)
	-----	-----
Net cash used in operating activities	(8,251)	(9,450)
	-----	-----
Cash flows from investing activities:		
Purchases of property and equipment	(6,768)	(4,285)
Sale and maturities of short-term investments	12,508	7,780
	-----	-----
Net cash provided by investing activities	5,740	3,495
	-----	-----
Cash flows from financing activities:		
Notes payable repayments	--	(1,538)
Additions to long-term debt borrowings	--	24,470
Repayment of long-term debt	(116)	(71)
Proceeds from sale of common stock	7,500	17,325
Proceeds from issuance of common stock (upon exercise of stock options and warrants)	569	327
	-----	-----
Net cash provided by financing activities	7,953	40,513
	-----	-----
Net increase in cash and cash equivalents	5,442	34,588
	-----	-----
Cash and cash equivalents, beginning of the period	\$ 15,044	\$ 11,448
	-----	-----
Cash and cash equivalents, end of the period	\$ 20,486	\$ 46,006
	=====	=====
Cash paid for interest	\$ 251	\$ 87
	=====	=====

The accompanying notes are an integral part of these financial statements.

NOTES TO FINANCIAL STATEMENTS

Six Months Ended

June 30, 2002 and June 30, 2001

Note 1. The financial statements included herein have been prepared by the

Company, without audit, pursuant to the rules and regulations of the Securities and Exchange Commission. Certain information and disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations; however, the Company believes that the disclosures are adequate to make the information presented not misleading. It is suggested that these financial statements be read in conjunction with the financial statements and the notes thereto included in the Company's latest annual report on Form 10-K. The results of operations for the six months ended June 30, 2002, are not necessarily indicative of the results of operations expected for the year ending December 31, 2002.

Impax Laboratories, Inc.'s ("IMPAX", "we" "us" or "the Company") main business is the development, manufacturing and marketing of specialty prescription pharmaceutical products utilizing its own formulation expertise and unique drug delivery technologies. The Company is currently marketing twenty-four products, has seventeen applications under review with the Food and Drug Administration (FDA), ten of these filings being made under Paragraph IV of the Hatch-Waxman Amendments, and four of these seventeen ANDAs have received tentative approval from the FDA. The Company has approximately eighteen additional products under development.

We have experienced, and expect to continue to experience, operating losses and negative cash flow from operations and our future profitability is uncertain. We do not know whether or when our business will ever be profitable or generate positive cash flow, and our ability to become profitable or obtain positive cash flow is uncertain. We have generated minimal revenues to date and have experienced operating losses and negative cash flow from operations since our inception. As of June 30, 2002, our accumulated deficit was \$81,661,000 and we had outstanding indebtedness in an aggregate principal amount of \$30,736,000. To remain operational, we must, among other things:

- o continue to obtain sufficient capital to fund our operations;
- o obtain from the FDA approval for our products;
- o prevail in patent infringement litigations in which we are involved;
- o successfully launch our new products; and
- o comply with the many complex governmental regulations that deal with virtually every aspect of our business activities.

We expect to incur significant operating expenses, particularly research and development and sales and marketing expenses, for the foreseeable future in order to execute our business plan. We, therefore, anticipate that such operating expenses, as well as planned capital expenditures, will constitute a material use of our cash resources.

Although our existing cash, cash equivalents, and short-term investments are expected to decline during 2002, we believe that our existing balances will be sufficient to meet our operational plan for at least the next twelve months. We may, however, seek additional financing in order to primarily fund our business plan in the brand name pharmaceutical area. We are currently negotiating a \$25 million revolving line of credit to partially fund our working capital requirements. However, we may be unable to finalize the revolving line of credit on terms acceptable to us, or at all.

To date, the Company has funded its research and development and other operating activities through equity and debt financings.

Note 2. The major highlights of the six months ended June 30, 2002, operational

activity included the following:

o In February 2002, the FDA tentatively approved the Company's ANDA for a generic version of Tricor(R) (Fenofibrate), Micronized. Tricor (R) is marketed by Abbott Laboratories ("Abbott"). The tentative approval covers 67mg, 134mg, and 200mg capsules. Final approval is contingent upon the earlier of (1) the settlement of pending patent infringement litigation brought by Abbott against IMPAX, or (2) the expiration of the 30 month stay process under the Hatch-Waxman Amendments, and the expiration of any generic marketing exclusivity. Final approval is also dependent upon FDA's evaluation of any new information it receives subsequent to this tentative approval.

o In February 2002, the FDA accepted our filing of an ANDA for a generic version of Allegra-D(R) (Fexofenadine HCl/Pseudoephedrine HCl) Extended Release 60mg/120mg Tablets (IMPAX's eighth Paragraph IV filing). In March 2002, Aventis Pharmaceuticals Inc., which markets Allegra-D(R) for the relief of symptoms associated with seasonal rhinitis in adults and children

12 years of age and older, filed a lawsuit against us in the United States District Court in Delaware alleging patent infringement related to our subject filing. U.S. sales of Allegra-D(R) Extended Release Tablets were over \$350 million in 2001.

o Also in February 2002, the FDA accepted our filing of an ANDA for a generic version of Oxycontin(R) (Oxycodone HCl) Extended Release 80mg Tablets (IMPAX's ninth Paragraph IV filing). Purdue Pharma markets Oxycontin(R) for the management of moderate-to-severe pain. U.S. sales of Oxycontin(R) Extended Release 80mg Tablets were over \$400 million in 2001. In April 2002, Purdue Pharma L.P. filed a lawsuit against us alleging patent infringement related to IMPAX's earlier filing of an ANDA for a generic version of Oxycontin(R) (Oxycodone HCl) Extended Release 80mg Tablets.

o In March 2002 and June 2002, under the terms of a strategic alliance announced in June 2001, we issued an aggregate of 883,068 shares of IMPAX common stock to a subsidiary of Teva Pharmaceutical Industries Ltd. ("TEVA"), for net proceeds to the Company of approximately \$7.5 million. Together with the shares sold in 2001, TEVA purchased a total of 1,462,083 shares, or approximately 3% of total shares of common stock outstanding. A Form S-3 Registration Statement registering these shares was filed with the Securities and Exchange Commission (SEC) on July 23, 2002.

o Also in March 2002, the FDA approved our ANDA to market Fludrocortisone Acetate Tablets, a generic version of Florinef(R), which is marketed by Monarch Pharmaceuticals, a division of King Pharmaceuticals, as partial replacement for primary and secondary adrenocortical insufficiency in Addison's disease. Florinef(R) sales in 2001 were approximately \$27 million. Our Global Pharmaceuticals division began marketing the product immediately.

o While the Company submitted its first brand filing as an ANDA in April 2002, based on discussions with FDA regarding the file, it subsequently withdrew the application and is planning to resubmit it as an NDA. Additionally, good progress has been made in formulation development for three other brand products with IND filings scheduled during the next 12 months for at least two of the three products.

o In May 2002, the FDA tentatively approved our ANDAs for generic versions of Claritin-D(R)24-Hour (loratadine/ pseudoephedrine sulfate, 10mg/240mg) Extended Release Tablets and Claritin-D(R)12-Hour (loratadine/ pseudoephedrine sulfate, 5mg/120mg) Extended Release Tablets. Both products are marketed by Schering-Plough Corporation for the relief of symptoms of seasonal allergic rhinitis (hay fever). Final approval is contingent upon the earlier of (1) the resolution of pending patent-infringement litigation brought by Schering-Plough against IMPAX, or (2) the expiration of the 30-month stay process under the Hatch-Waxman Amendments; and the expiration of any generic marketing exclusivity for the Claritin-D(R) 24-Hour. Final approval is also dependent upon FDA's evaluation of any new information subsequent to these tentative approvals. In March 2002, Schering-Plough announced that it filed with the FDA an application to switch all of the prescription Claritin formulations to over-the-counter (OTC). If Schering-Plough's application is approved by the FDA, we may not be able to market our generic versions of the Claritin formulations as prescription drugs.

o In June 2002, we signed a semi-exclusive Development, License and Supply Agreement with Wyeth, acting through its Wyeth Consumer Healthcare Division, relating to our generic versions of Claritin-D(R) 12-Hour (loratadine/pseudoephedrine sulfate, 5mg/120mg) Extended Release Tablets and Claritin-D(R) 24-Hour (loratadine/pseudoephedrine sulfate, 10mg/240mg) Extended Release Tablets for the OTC market.

o Also in June 2002, we signed a non-exclusive Licensing, Contract Manufacturing and Supply Agreement with Schering-Plough Corporation relating to Claritin-D(R) 12-Hour (loratadine/pseudoephedrine sulfate) Extended Release Tablets, 5mg/120mg for the OTC market. This agreement does not resolve the ongoing patent litigation between Schering-Plough and IMPAX to decide whether we may market our generic Claritin-D(R) 12-Hour product or manufacture such a product for companies other than Schering-Plough prior to the expiration of a Schering-Plough patent in 2004.

Note 3. The construction of the new manufacturing facility in Hayward,

California was completed this quarter. The total construction cost was approximately \$12,339,900, including capitalized interest cost of approximately \$595,000; approximately \$1,136,000 of retention was paid in July 2002.

Note 4. In July 2002, we began marketing a new product, Minocycline

Hydrochloride Capsules, USP 75mg, a generic version of Dynacin(R), marketed by Medicis Pharmaceutical Corporation, and we also reintroduced the Minocycline Hydrochloride Capsules, USP 100mg, a generic version of Minocin(R), marketed by Lederle Pharmaceutical Division of Wyeth Corporation. Both products are antibiotics and are prescribed for the treatment of infectious diseases and as adjunctive therapy in severe acne.

Note 5. In July 2002, the FDA tentatively approved our ANDA for a generic

version of Rilutek(R) (Riluzole) 50mg tablets. Aventis Pharmaceutical Products, Inc. markets Rilutek(R) for the treatment of amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's disease. According to IMS Health, U.S. sales of Rilutek(R) were \$35 million for the twelve months ended March 31, 2002. Final approval is contingent upon the expiration of Orphan Drug Exclusivity on December 12, 2002, as well as FDA's evaluation of any new information subsequent to this tentative approval.

We filed a declaratory judgment complaint against Aventis in the United States District Court for the District of Delaware to obtain a judicial declaration of patent invalidity and/or non-infringement with respect to Patent No. 5,527,814, which was recently listed by Aventis in the FDA "Orange Book".

Note 6. The Company adopted SFAS 142 effective January 1, 2002. The Company no

longer amortizes goodwill and will perform an annual impairment assessment of goodwill. With the adoption of SFAS 142, the Company completed a transitional impairment assessment of goodwill as of January 1, 2002 and there was no impairment. The Company recorded \$876,000 as goodwill amortization expense for the three months ended June 30, 2001 and \$1,752,000 for the six months ended June 30, 2001, or the equivalent of \$(0.02) and \$(0.05) per (basic and diluted) share, respectively. The Company's net loss and net loss per share, respectively, would have been \$5,274,000 and \$(0.13) per (basic and diluted) share for the three months ended June 30, 2001 and \$9,736,000 and \$(0.26) per (basic and diluted) share for the six months ended June 30, 2001, had the nonamortization provisions of SFAS 142 been effective at the beginning of fiscal 2001.

Note 7. The Company reports both basic earnings per share, which is based on the

weighted-average number of common shares outstanding, and diluted earnings per share, which is based on the weighted-average number of common shares outstanding and all dilutive potential common shares outstanding. Because the Company had net losses in each of the years presented, only the weighted average of common shares outstanding has been used to calculate both basic earnings per share and diluted earnings per share, as inclusion of the potential common shares would be anti-dilutive.

Mandatorily redeemable convertible stock of 1,500,000 shares of common stock (on an as-converted basis), warrants to purchase 2,773,266 shares of common stock, and stock options to purchase 4,396,190 shares of common stock were outstanding at June 30, 2002, but were not included in the calculation of diluted earnings per share, as their effect would be anti-dilutive.

Note 8. Our inventory consists of the following:

	June 30, 2002	December 31, 2001
	-----	-----
	(in thousands)	
Raw materials.....	\$ 1,952	\$ 2,004
Finished goods.....	2,886	1,634
	-----	-----
	4,838	3,638
Less: Reserve for obsolete inventory and net realizable value.....	150	150
	-----	-----
	\$ 4,688	\$ 3,488
	=====	=====

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The information in this report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Such statements are based upon current expectations that involve risks and uncertainties. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. For example, words such as "may," "will," "should," "estimates," "predicts" "potential," "continue," "strategy," "believes," "anticipates," "plans," "expects," "intends," and similar expressions are intended to identify forward-looking statements. Our actual results and the timing of certain events may differ significantly from the results discussed in the forward-looking statements. Factors that might cause or contribute to such a discrepancy include, but are not limited to, risks and uncertainties, including the difficulty of predicting FDA filings and approvals, acceptance and demand for new pharmaceutical products, the impact of competitive products and pricing, new product development and launch, reliance on key strategic alliances, uncertainty of patent litigation filed against us, availability of raw materials, the regulatory environment, fluctuations in operating results and other risks detailed from time to time in the Company's filings with the Securities and Exchange Commission.

Critical Accounting Policies

Accounting For and Recoverability of Goodwill

In July 2001, the Financial Accounting Standards Board ("FASB") issued SFAS No. 142, "Goodwill and Other Intangible Assets" ("SFAS 142"). The provisions of SFAS 142 are summarized in Note 6 to the interim consolidated financial statements. The new criteria for recording intangible assets separate from goodwill did not require us to reclassify any of our intangible assets. Our transitional

impairment test indicated that there was no impairment of goodwill upon adoption of SFAS 142. Assuming the nonamortization provisions of SFAS 142 had been effective at the beginning of fiscal 2001, the net loss for the three and six months ended June 30, 2001 would have decreased by \$876,000 and \$1,752,000 respectively, representing the reduction in goodwill amortization.

Effective January 1, 2002, we evaluate the recoverability and measure the possible impairment of our goodwill under SFAS 142. The impairment test is a two-step process that begins with the estimation of the fair value of the reporting unit. The first step screens for potential impairment, and the second step measures the amount of the impairment, if any. Our estimate of fair value considers publicly available information regarding the market capitalization of our Company, as well as (i) publicly available information regarding comparable publicly-traded companies in the generic pharmaceutical industry, (ii) the financial projections and future prospects of our business, including its growth opportunities and likely operational improvements, and (iii) comparable sales prices, if available. As part of the first step to assess potential impairment, we compare our estimate of fair value for the Company to the book value of our consolidated net assets. If the book value of our consolidated net assets is greater than our estimate of fair value, we would then proceed to the second step to measure the impairment, if any. The second step compares the implied fair value of goodwill with its carrying value. The implied fair value is determined by allocating the fair value of the reporting unit to all of the assets and liabilities of that unit as if the reporting unit had been acquired in a business combination, and the fair value of the reporting unit was the purchase price paid to acquire the reporting unit. The excess of the fair value of the reporting unit over the amounts assigned to its assets and liabilities is the implied fair value of goodwill. If the carrying amount of the reporting unit goodwill is greater than its implied fair value, an impairment loss will be recognized in the amount of the excess.

On a quarterly basis, we perform a review of our business to determine if events or changes in circumstances have occurred which could have a material adverse effect on the fair value of the Company and its goodwill. If such events or changes in circumstances were deemed to have occurred, we would consult with one or more valuation specialists in estimating the impact on our estimate of fair value. We believe the estimation methods are reasonable and reflective of common valuation practices.

General

We are a technology based, specialty pharmaceutical company applying formulation and development expertise, as well as our drug delivery technology, to the development of controlled-release and niche generics, in addition to the development of branded products. We currently market twenty-four generic products and have seventeen ANDA filings pending at the FDA that address more than \$9.0 billion in U.S. branded product sales in 2001. Ten of these filings were made under Paragraph IV of the Hatch-Waxman Amendments and four of these seventeen ANDAS have received tentative approval from the FDA. We have approximately eighteen additional products under development.

Results of Operations

We have incurred net losses in each year since our inception. We had an accumulated deficit of \$81,661,000 at June 30, 2002.

THREE MONTHS ENDED JUNE 30, 2002, COMPARED TO THREE MONTHS ENDED JUNE 30, 2001

Overview

The net loss for the three months ended June 30, 2002, was \$5,938,000 as compared to \$6,150,000 for the three months ended June 30, 2001, including goodwill amortization expense of approximately \$876,000. The increase in the net loss of \$664,000, excluding 2001 goodwill amortization expense, was primarily due to higher research and development expenses and infrastructure costs related to the new manufacturing facility in Hayward, California, and expansion of our sales and marketing capabilities, partially offset by higher revenues.

Revenues

The net sales for the three months ended June 30, 2002, were \$5,145,000 as compared to \$1,136,000 for the same period in 2001. The higher sales were primarily due to the sale of two newly approved products: Terbutaline Sulfate Tablets (launched in June 2001) and Fludrocortisone Acetate Tablets (launched in March 2002).

Cost of Sales

The cost of sales for the three months ended June 30, 2002, was \$3,982,000 as compared to \$1,992,000 for the same period in 2001. The overall increase in cost of sales was primarily due to material costs as a result of increased net sales.

Gross Margin

Due primarily to higher net sales which offset the increase in the infrastructure costs related to the new manufacturing facility in Hayward, California, we realized a gross margin of \$1,163,000 for the three months ended June 30, 2002, as compared to a negative gross margin of \$856,000 for the same period in 2001.

Research and Development Expenses

The research and development expenses for the three months ended June 30, 2002, were \$4,476,000 less reimbursement of \$138,000 by TEVA under the strategic alliance agreement signed in June 2001, as compared to \$2,415,000 for the same period in 2001. The increase of approximately 85% over 2001 was primarily due to higher personnel, material and biostudy costs.

Selling Expenses

The selling expenses for the three months ended June 30, 2002, were \$646,000 as compared to \$806,000 for the same period in 2001. The decrease in selling expenses as compared to 2001 was primarily due to a \$200,000 expense related to the TEVA agreement in 2001, partially offset by additional personnel, advertising, and freight costs.

General and Administrative Expenses

The general and administrative expenses for the three months ended June 30, 2002, were \$1,939,000 as compared to \$2,236,000 for the same period in 2001, including goodwill amortization expenses of approximately \$876,000. The increase in 2002 general and administrative expenses as compared to 2001, excluding 2001 goodwill amortization expense, was primarily due to higher personnel costs, professional fees and insurance premiums.

Interest Income

Interest income for the three months ended June 30, 2002, was \$167,000 as compared to \$161,000 for the same period in 2001, primarily due to higher cash equivalents and short term investments, partially offset by lower interest rates.

Interest Expense

Interest expense for the three months ended June 30, 2002, was \$366,000 as compared to \$37,000 for the same period in 2001, primarily due to the \$438,000 of interest accrued on the refundable deposit from TEVA and the interest payable on the two Cathay Bank loans. The 2002 interest expense excludes \$222,000 in capitalized interest related to the construction of the San Antonio Street - Hayward, California building.

Net Loss

The net loss for the three months ended June 30, 2002, was \$5,938,000 as compared to \$6,150,000 for the same period in 2001, including goodwill amortization expense of approximately \$876,000. The increase in net loss of \$664,000, excluding 2001 goodwill amortization expense, was primarily due to higher research and development and infrastructure costs related to the new manufacturing facility in Hayward, California, partially offset by higher revenues.

SIX MONTHS ENDED JUNE 30, 2002, COMPARED TO SIX MONTHS ENDED JUNE 30, 2001

Overview

The net loss for the six months ended June 20, 2002, was \$11,359,000 as compared to \$11,488,000 for the six months ended June 30, 2001, including goodwill amortization expense of approximately \$1,752,000. The increase in the net loss of \$1,623,000, excluding 2001 goodwill amortization expense, was primarily due to higher research and development expenses and infrastructure costs related to the new manufacturing facility in Hayward, California, and expansion of our sales and marketing capabilities, partially offset by higher revenues.

Revenues

The net sales for the six months ended June 30, 2002, were \$8,577,000 as compared to \$2,908,000 for the same period in 2001. The higher sales were primarily due to the sale of two newly approved products: Terbutaline Sulfate Tablets (launched in June 2001) and Fludrocortisone Acetate Tablets (launched in March 2002).

Cost of Sales

The cost of sales for the six months ended June 30, 2002, was \$7,121,000 as compared to \$4,268,000 for the same period in 2001. The overall increase in cost of sales was primarily due to material costs as a result of increased net sales. Included in the cost of sales are startup costs of the new manufacturing facility in Hayward, California, and fixed, unabsorbed costs of the excess plant capacity in Philadelphia, Pennsylvania.

Gross Margin

Due primarily to higher net sales which offset the increase in the infrastructure costs related to the new manufacturing facility in Hayward, California, we realized a gross margin of \$1,456,000 for the six months ended June 30, 2002, as compared to a negative gross margin of \$1,360,000 for the same period in 2001.

Research and Development Expenses

The research and development expenses for the six months ended June 30, 2002, were \$7,366,000 less reimbursement of \$304,000 by TEVA under the strategic alliance agreement signed in June 2001, as compared to \$5,010,000 for the same period in 2001. The increase of approximately 47% over 2001 was primarily due to higher personnel, material and biostudy costs.

Selling Expenses

The selling expenses for the six months ended June 30, 2002, were \$1,304,000 as compared to \$1,123,000 for the same period in 2001. The increase in selling expenses as compared to 2001, which included a \$200,000 expense related to the TEVA agreement in 2001, was primarily due to additional personnel, advertising, and freight costs.

General and Administrative Expenses

The general and administrative expenses for the six months ended June 30, 2002, were \$4,109,000 as compared to \$4,395,000 for the same period in 2001, including goodwill amortization expense of approximately \$1,752,000. The increase in 2002 general and administrative expenses as compared to 2001, excluding 2001 goodwill amortization expense, was primarily due to higher personnel costs, professional fees, insurance premiums, and software expenses.

Interest Income

Interest income for the six months ended June 30, 2002, was \$402,000 as compared to \$423,000 for the same period in 2001, primarily due to lower interest rates.

Interest Expense

Interest expense for the six months ended June 30, 2002, was \$733,000 as compared to \$87,000 for the same period in 2001, primarily due to the \$876,000 of interest accrued on the refundable deposit from TEVA and the interest payable on the two Cathay Bank loans. The 2002 interest expense excludes \$394,000 in capitalized interest related to the construction of the San Antonio Street - Hayward, California building.

Net Loss

The net loss for the six months ended June 30, 2002, was \$11,359,000 as compared to \$11,488,000 for the same period in 2001, including goodwill amortization expense of approximately \$1,752,000. The increase in net loss of \$1,623,000, excluding 2001 goodwill amortization expense, was primarily due to higher research and development and infrastructure costs related to the new manufacturing facility in Hayward, California, and expansion of our sales and marketing capabilities, partially offset by higher revenues.

Liquidity and Capital Resources

As of June 30, 2002, we had \$20,486,000 in cash and cash equivalents, and \$7,914,000 in short-term investments. The short-term investments mature within a year and we believe that the market risk arising from holding these investments is not material.

The net cash provided by financing activities for the six months ended June 30, 2002, was approximately \$7,953,000 consisting of the \$7,500,000 sale of common stock to TEVA, and proceeds from issuance of common stock upon exercise of stock options and warrants. During the six months ended June 30, 2002, the sale and maturities of short-term investments of \$12,508,000 funded the net capital expenditures of approximately \$6,768,000 and the net cash used in operating activities of \$8,251,000.

We have no interest rate or derivative hedging contracts and material foreign exchange or commodity price risks. We are also not party to any off-balance-sheet arrangements, other than operating leases.

We expect to incur significant operating expenses, particularly research and development and sales and marketing expenses, for the foreseeable future in order to execute our business plan. We, therefore, anticipate that such operating expenses, as well as planned capital expenditures, will constitute a material use of our cash resources.

We anticipate obtaining, during the third quarter of 2002, a \$25 million revolving line of credit to partially fund our working capital requirements. However, we may be unable to obtain this revolving line of credit on terms acceptable to us, or at all.

Although our existing cash, cash equivalents, and short-term investments are expected to decline during 2002, we believe that our existing balances will be sufficient to meet our operational plan for at least the next twelve months. We may, however, seek additional financing in order to primarily fund our business plan in the brand name pharmaceutical area.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

The Company's investment portfolio consists of cash and cash equivalents and marketable securities stated at cost which approximates market value. The primary objective of the Company's investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, the Company maintains its portfolio in a variety of high credit quality securities, including U.S. Government securities, treasury bills, short-term commercial paper, and highly rated money market funds. One hundred percent of the Company's portfolio matures in less than one year. The carrying value of the investment portfolio approximates the market value at June 30, 2002. The Company's debt instruments at June 30, 2002, are subject to fixed interest rates and principal payments. We believe that the fair value of our fixed rate long-term debt and refundable deposit approximates their carrying value of approximately \$29 million at June 30, 2002. While changes in market interest rates may affect the fair value of our fixed rate long-term debt, we believe the effect, if any, of reasonably possible near-term changes in the fair value of such debt on the Company's financial statements will not be material.

We do not use derivative financial instruments and have no material foreign exchange or commodity price risks.

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Patent Litigation

There has been substantial litigation in the pharmaceutical, biological, and biotechnology industries with respect to the manufacture, use and sale of new products that are the subject of conflicting patent rights. Most of the brand name controlled-release products for which we are developing generic versions are covered by one or more patents. Under the Hatch-Waxman Amendments, when a drug developer files an ANDA for a generic drug, and the developer believes that an unexpired patent which has been listed with the FDA as covering that brand name product will not be infringed by the developer's product or is invalid or unenforceable, the developer must so certify to the FDA. That certification must also be provided to the patent holder, who may challenge the developer's certification of non-infringement, invalidity or unenforceability by filing a suit for patent infringement within 45 days of the patent holder's receipt of such certification. If the patent holder files suit, the FDA can review and approve the ANDA, but is prevented from granting final marketing approval of the product until a final judgment in the action has been rendered or 30 months from the date the certification was received, whichever is sooner. Should a patent holder commence a lawsuit with respect to an alleged patent infringement by us, the uncertainties inherent in patent litigation make the outcome of such litigation difficult to predict. The delay in obtaining FDA approval to market our product candidates as a result of litigation, as well as the expense of such litigation, whether or not we are successful, could have a material adverse effect on our results of operations and financial position. In addition, there can be no assurance that any patent litigation will be resolved prior to the 30-month period. As a result, even if the FDA were to approve a product upon expiration of the 30-month period, we may be prevented from marketing that product if patent litigation is still pending.

Litigation has been filed against us in connection with nine of our Paragraph IV filings. The outcome of such litigation is difficult to predict because of the uncertainties inherent in patent litigation.

Prilosec (Omeprazole) Litigation

In May 2000, AstraZeneca AB and four of its related companies filed suit against us in the United States District Court in Delaware, claiming our submission of an ANDA for Omeprazole Delayed Release Capsules, 10mg and 20mg, constitutes infringement of six U.S. patents relating to the AstraZeneca Prilosec product. In February 2001, AstraZeneca filed a second action against us in the same court making the same claim against our Omeprazole Delayed Release Capsules, 40mg. These actions seek an order enjoining us from marketing Omeprazole Delayed Release Capsules, 10mg, 20mg and 40mg, until February 4, 2014, and awarding costs and attorney fees. There is no claim for damages. AstraZeneca has filed essentially the same lawsuit against nine other generic pharmaceutical companies (Andrx, Genpharm, Cheminor, Kremers, LEK, Eon, Mylan, Apotex and Zenith).

Due to the number of these cases, a multi-district litigation proceeding, *In re Omeprazole MDL-1291*, has been established to coordinate pretrial proceedings. We were added to the multi-district proceeding in September 2000. In the multi-district litigation, the district court ruled that one of the six patents-in-suit is not infringed by the sale of a generic Omeprazole product and another patent-in-suit is invalid. These rulings effectively eliminate two of the six patents from the litigation. In March, 2000, AstraZeneca advised all of the defendants in the multidistrict litigation that AstraZeneca added four new patents to the FDA's Orange Book as Omeprazole patents. We filed Paragraph IV Certifications asserting that our Omeprazole Delayed Release Capsules will not infringe valid claims of the four newly listed patents. The forty-five (45) day period for AstraZeneca to file suit against Impax under the four newly listed patents expired on August 6, 2001. AstraZeneca did not file suit on these patents against us or any other generic pharmaceutical company that filed Paragraph IV Certifications for these patents.

Presently, we and five of the other generic company defendants are awaiting the outcome of the trial involving AstraZeneca and the first four generic company defendants who were sued a year earlier than us and the other generic company defendants. The trial began in December 2001, concluded in June 2002, and is expected to lead to a decision by the court in the third quarter of this year. Once this first trial is concluded, discovery and other pretrial matters will proceed with respect to us and the other remaining defendants.

We believe we have defenses to the claims made by AstraZeneca in the lawsuit based upon non-infringement and invalidity of the patents-in-suit.

Tricor (Fenofibrate) Litigation

In 2000, Abbott Laboratories, Fournier Industrie et Sante, and a related company filed two actions against us in the United States District Court in Chicago, Illinois, claiming that our submission of an ANDA for Fenofibrate (Micronized) Capsules, 67mg and 134mg constitutes infringement of a U.S. patent owned by Fournier and exclusively licensed to Abbott, relating to Abbott's Tricor product. In December 2000, Abbott and Fournier filed a third action against us in the same court making the same claims against our 200mg Fenofibrate (Micronized) Capsules. These actions seek an injunction preventing us from marketing our fenofibrate products until January 19, 2009, and an award of damages for any commercial manufacture, use or sale of our fenofibrate products, together with costs and attorney fees. Abbott and Fournier previously filed essentially the same lawsuit against Novopharm/TEVA, also in the United States District Court in Chicago.

We filed an answer to Abbott's complaint in April 2001. Our answer asserts that Abbott's patent is invalid and not enforceable against us. The parties in this matter have conducted discovery but the court has not set a trial date. We believe we have defenses based upon non-infringement, invalidity and unenforceability.

In a related litigation concerning the same patent, the U.S. District Court of Illinois granted, in March 2001, summary judgment of non-infringement regarding Novopharm/TEVA's ANDA for Fenofibrate (Micronized) Capsules.

In April 2002, we filed a Motion for Summary Judgment to finally resolve this litigation without the need for a trial. The Motion is based in part on the recent decision won by Novopharm/TEVA. Our motion was fully briefed as of July 12, 2002.

Wellbutrin SR and Zyban (Bupropion) Litigation

In October 2000, Glaxo Wellcome Inc. filed a lawsuit against us in the United States District Court, Northern District of California, claiming that our submission of two ANDAs for Bupropion Hydrochloride constitutes infringement of several patents owned by Glaxo relating to Glaxo's Wellbutrin SR and Zyban products. The action seeks to enjoin us from receiving approval of our application prior to the expiration date of Glaxo's patent, award Glaxo preliminary and final injunctions enjoining us from continued infringement of

its patent, and award further relief as the Court may deem proper. Glaxo has filed suit against Andrx, Watson and EON (only with regard to Wellbutrin SR) for similar ANDA filings. We filed our answer and counterclaim to Glaxo's complaint in November 2000. We filed a motion for Summary Judgment, which the court heard in November 2001. To date, the Court has not ruled on our motion for Summary Judgment nor entered a final date for the end of discovery. We believe that we have strong defenses to the claims made by Glaxo in the lawsuit based on non-infringement and invalidity. At the request of the Court, in July 2002, both sides submitted briefs on the impact of the recent United States Supreme Court decision in *Festo vs. Shoketsu Kinzoku Kogyo Kabushi Co., et al* to the pending motion for summary judgment. In related litigation concerning the same patents, a federal judge in Florida has ruled that Andrx Pharmaceuticals does not infringe the Glaxo patents covering Bupropion. Also, Glaxo had decided to settle its Bupropion litigation with Watson Pharmaceuticals in July 2001 on terms that are confidential.

Claritin (Loratadine) Litigation

In January 2001, Schering-Plough Corporation ("Schering") sued us in the United States District Court for the District of New Jersey, alleging that our proposed loratadine and pseudoephedrine sulfate 24-hour extended release tablets, containing 10mgs of loratadine and 240mgs of pseudoephedrine sulfate, infringe their U.S. Patent Nos. 4,659,716 and 5,314,697. Schering has sought to enjoin us from obtaining FDA approval to market our loratadine 24-hour product until the 5,314,697 patent expires in 2012. Schering has also sought monetary damages should we use, sell, or offer to sell our loratadine 24-hour product prior to the expiration of this patent.

We filed our answer to the complaint denying that we infringe any valid and/or enforceable claim of their patents. Based in part on statements made by Schering during the prosecution of its application for the 5,314,697 patent, we assert that Schering should not succeed on its claims that our loratadine 24-hour product infringes this patent. Additionally, we do not believe that Schering's claims related to its 4,659,716 patent, which relate to an active metabolite of loratadine produced in the body upon ingestion of loratadine, cover the generic loratadine products.

In January 2001, Schering sued us in the United States District Court for the District of New Jersey, alleging that our proposed orally-disintegrating loratadine ODT product infringes claims of the 4,659,716 patent. Schering has sought to enjoin us from obtaining approval to market our loratadine ODT product until this patent expires in 2004. Schering has also sought monetary damages should we use, sell, or offer to sell our loratadine ODT product prior to the expiration of their patent. We filed the answer to the complaint denying that we infringe any valid and/or enforceable claim of their patent.

In February 2001, Schering sued us in the United States District Court for the District of New Jersey, alleging that our proposed loratadine and pseudoephedrine sulfate 12-hour extended release tablets, containing 5mgs of loratadine and 120mgs of pseudoephedrine sulfate, infringes claims of the 4,659,716 patent. Schering has sought to enjoin us from obtaining approval to market our loratadine 12-hour product until this patent expires in 2004. Schering has also sought monetary damages should we use, sell, or offer to sell our loratadine product prior to the expiration of their patent. We filed the answer to the complaint denying that we infringe any valid and/or enforceable claim of their 4,659,716 patent.

These three cases have been consolidated for the purposes of discovery with seven other cases in the District of New Jersey, in which Schering sued other companies who sought FDA approval to market generic loratadine products. The parties have concluded discovery related to the 4,659,716 patent. The parties (IMPAX and Andrx) continue discovery related to the 5,314,697 patent and the court has not yet entered a schedule for completion of this discovery.

On March 8, 2002, Schering announced that it had filed with the FDA an application to switch all of the Claritin formulations from prescription to OTC. If Schering's application is approved by the FDA, we may not be able to market our generic versions of the Claritin formulation as prescription drugs. Oral argument on the dispositive motions related to the 4,659,716 patent was heard before the judge on June 25, 2002 and a decision is expected before December 2002.

Allegra-D(R) (Fexofenadine) Litigation

In March 2002, Aventis Pharmaceuticals, Inc. ("Aventis") filed a lawsuit against us in the United States District Court for the District of New Jersey and filed a virtually identical complaint in the United States District Court for the District of Delaware claiming our submission of an ANDA for a generic version of Allegra-D(R) (Fexofenadine HCl/Pseudoephedrine HCl) Extended Release 60mg/120mg Tablets constitutes infringement of six Allegra-D(R) patents. We have yet to file an answer in the litigation and no discovery has been scheduled. We intend to vigorously defend our product and believe that we have strong defenses to the claims made by Aventis in the lawsuit.

Oxycontin(R) (Oxycodone HCl) Litigation

In April 2002, Purdue Pharma L.P. filed a lawsuit against us in the United States Southern District Court of New York alleging patent infringement related to our filing of an ANDA for a generic version of Oxycontin(R) (Oxycodone HCl) Extended Release 80mg Tablets. We have yet to file an answer in the litigation

and no discovery has been scheduled. We intend to vigorously defend our product and believe that we have strong defenses to the claims made by Purdue Pharma in the lawsuit.

Rilutek(R) (Riluzole) 50mg Litigation

In May 2002, we filed an ANDA for a generic version of Rilutek(R) (Riluzole) 50mg tablets. In June 2002, we filed a lawsuit against Aventis Pharmaceuticals Inc. ("Aventis") alleging that Aventis' patent no. 5,527,814 related to Rilutek(R) is invalid and that IMPAX has not infringed on this patent by filing its ANDA. Aventis is yet to respond to this lawsuit.

Other than the patent litigations described above, we are not aware of any other material pending or threatened legal actions, private or governmental, against us.

Insurance

As part of our patent litigation strategy, we have obtained up to \$7 million of patent infringement liability insurance from American International Specialty Line Company (an affiliate of AIG International). This litigation insurance covers us against the costs associated with patent infringement claims made against us relating to seven of the ten ANDAs we filed under Paragraph IV of the Hatch-Waxman Amendments. At present, we believe this insurance coverage is sufficient for our legal defense costs related to these seven ANDAs. However, we do not believe that this type of litigation insurance will be available to us on acceptable terms for our other current or future ANDAs.

Product liability claims by customers constitute a risk to all pharmaceutical manufacturers. We carry \$10 million of product liability insurance for our own manufactured products. This insurance may not be adequate to cover any product liability claims to which we may become subject.

ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS

On June 17, 2002, the Company sold, in a private placement, 463,135 shares of Common Stock to a subsidiary of TEVA for an aggregate consideration of \$3,750,000. The Company relied on the exemption from registration under the Securities Act of 1933 (the "Act") provided by Section 4(2) of the Act.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

At the Company's Annual Meeting of Stockholders held on May 6, 2002, the following actions were approved, by the votes indicated:

a) Ten directors were elected:

Leslie Z. Benet, Ph.D.	43,096,064	For	99,161	Withhold authority
Robert L. Burr	42,969,997	For	225,228	Withhold authority
Barry R. Edwards	41,753,417	For	1,441,808	Withhold authority
David J. Edwards	42,967,033	For	228,192	Withhold authority
Nigel Fleming, Ph.D.	43,096,564	For	98,661	Withhold authority
Charles Hsiao, Ph.D.	41,755,228	For	1,439,997	Withhold authority
Larry Hsu, Ph.D.	41,388,379	For	1,806,846	Withhold authority
Michael Markbreiter	43,096,464	For	98,761	Withhold authority
Oh Kim Sun	43,096,264	For	98,961	Withhold authority
Michael G. Wokasch	43,096,264	For	98,961	Withhold authority

b) The 2002 Equity Incentive Plan was approved by the stockholders as follows:

28,878,594 For 1,615,108 Against 1,038,092 Abstaining

c) The appointment of PricewaterhouseCoopers LLP as the Company's independent accountants for the fiscal year ending December 31, 2002 was ratified, as follows:

42,899,377 For 274,930 Against 20,918 Abstaining

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits:

- 10.60 Development, License and Supply Agreement dated as of June 1, 2002 between Wyeth, acting through its Wyeth Consumer Healthcare Division, and Impax Laboratories, Inc. for loratadine/pseudoephedrine combination tablets.
- 10.61 Licensing, Contract Manufacturing & Supply Agreement between Schering Corporation and Impax Laboratories, Inc. dated June 18, 2002.

(b) None

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

IMPAX LABORATORIES, INC.

By: /s/ BARRY R. EDWARDS (Principal Executive Officer)

Co-Chief Executive Officer

By: /s/ CORNEL C. SPIEGLER (Principal Financial and
----- Accounting Officer)
Chief Financial Officer

DEVELOPMENT, LICENSE AND SUPPLY AGREEMENT

dated as of June 18, 2002

between

WYETH

acting through its Wyeth Consumer Healthcare Division

and

IMPAX LABORATORIES, INC.

for

Loratadine/Pseudoephedrine Combination Tablets

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THIS DEVELOPMENT, LICENSE AND SUPPLY AGREEMENT is made and entered into as of this 1st day of June 2002, between WYETH, a corporation organized and existing under the laws of Delaware, acting through its Wyeth Consumer Healthcare Division and having an address at Five Giralda Farms, Madison, New Jersey 07940 ("WCH") and IMPAX LABORATORIES, INC., a corporation organized and existing under the laws of Delaware and having an address at 3735 Castor Avenue, Philadelphia, Pennsylvania 19124 ("IMPAX").

RECITALS

WHEREAS, IMPAX has developed two loratadine/pseudoephedrine combination products and has filed an Abbreviated New Drug Application for each such product with the United States Food and Drug Administration;

WHEREAS, WCH wishes to license IMPAX's patents and technical information with respect to such loratadine/pseudoephedrine combination products and to have IMPAX supply WCH with such products for sale as over-the-counter drugs; and

WHEREAS, IMPAX is experienced in the manufacture of pharmaceutical products and is willing to grant such license and supply WCH with such products, all on the terms and subject to the conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual covenants and agreements set forth herein, and for good and valuable consideration the receipt and sufficiency of which are hereby acknowledged, the parties hereto hereby agree as follows:

ARTICLE I DEFINITIONS

1.1 Definitions. As used in this Agreement, the following capitalized terms have the meanings indicated below:

1.1.1 "Affiliate" means, in the case of either Party, any corporation, joint venture, or other business entity which directly or indirectly controls, is controlled by, or is under common control with that Party. "Control," as used in this Section 1.1.1, means having the power to direct, or cause the direction of, the management and policies of an entity, whether through ownership of voting securities, by contract or otherwise. Notwithstanding the foregoing, for purposes of this Agreement, the term "Affiliate" does not include entities in which a Party or its Affiliates owns a majority of the ordinary voting power to elect a majority of the board of directors but is restricted from electing such majority by contract or otherwise, until such time as such restrictions are no longer in effect.

1.1.2 "ANDA" means an Abbreviated New Drug Application, as defined in the FD&C Act and applicable FDA rules and regulations.

1.1.3 "Batch" means a Manufacturing run of Product which yields approximately one million two hundred thousand (1,200,000) tablets of Product, as the same may be amended from time to time by the mutual written agreement of the Parties.

1.1.4 "Certificate of Analysis" means the document identifying the results of the Methods of Analysis for a specific Batch of Product in the form agreed to by the Parties.

1.1.5 "CMC" has the meaning set forth in Section 3.1.1(ii).

1.1.6 "Commercially Reasonable Efforts" means efforts and resources normally used by a Party for a compound or product owned by it or to which it has rights, which is of similar market potential at a similar stage in its product life, taking into account the competitiveness of the marketplace, the proprietary position of the compound or product, the regulatory structure involved, the profitability of the applicable products, and other relevant factors. It is anticipated that the level of effort and resources may change at different times during the product life cycle of a compound or product.

1.1.7 "Competing Product" has the meaning set forth in Section 2.3.

1.1.8 "Confidential Information" means either WCH Confidential Information, IMPAX Confidential Information or both, as the context requires.

1.1.9 "Contract Year" means the period from the Effective Date through May 31, 2003 and each consecutive twelve (12) month period thereafter during the Term.

1.1.10 "Control" or "Controlled" in the context of intellectual property rights means rights to intellectual property sufficient to allow a grant of rights to a Party.

1.1.11 "Direct Development Cost" means (a) costs directly attributable to an activity (i.e., those costs which vary with such activity), including, but not limited to, direct labor and benefit expenses for such activity and consumable bulk and other materials, as determined in accordance with United States generally accepted cost accounting practices consistently applied, plus (b) fixed overhead costs allocable to the activity, including, but not limited to, direct benefit and labor expenses for technical services and support services, depreciation, maintenance and repairs and insurance costs associated with such activity, as determined in accordance with United States generally accepted cost accounting practices consistently applied. In no event shall any costs included in Direct Manufacturing Costs be included in Direct Development Costs.

1.1.12 "Direct Manufacturing Cost" means (a) costs directly attributable to Manufacturing, quality assurance and quality control related to a unit of Product on a per tablet basis, including, but not limited to, direct labor and benefit expenses for Manufacturing, and consumable bulk and other product materials, as determined in accordance with United States generally accepted cost accounting practices consistently applied, plus (b) fixed Manufacturing overhead costs allocable to the Product based on the actual percentage utilization (including start-up and shut-down time) of the capacity of the manufacturing facility, including, but not limited to, direct benefit and

labor expenses for technical services and support services, depreciation, maintenance and repairs and insurance costs associated with such utilization of the manufacturing facility, as determined in accordance with United States generally accepted cost accounting practices consistently applied. In no event shall charges for (i) idle capacity or underutilized facilities or (ii) any Direct Development Costs be included in Direct Manufacturing Costs.

1.1.13 "D-12 Product" means a twelve (12) hour extended release tablet containing 5 mg Loratadine and 120 mg Pseudoephedrine meeting the Specifications therefor.

1.1.14 "D-24 Product" means a twenty-four (24) hour extended release tablet containing 10 mg Loratadine and 240 mg Pseudoephedrine meeting the Specifications therefor.

1.1.15 "Effective Date" means the date determined pursuant to Section 14.10.

1.1.16 "Exclusive Territory" means the world, except the countries of China (including Hong Kong), Taiwan, Singapore, Malaysia, The Philippines, Indonesia, Myanmar, Brunei, Cambodia, Vietnam, Thailand, Laos and the Semi-Exclusive Territory.

1.1.17 "Facility" means IMPAX's facilities located at Hayward, California or any other facility located in the United States approved in writing by WCH for the Manufacture of Product, such approval not to be unreasonably withheld or delayed.

1.1.18 "FDA" means the United States Food and Drug Administration or any successor entity thereto.

1.1.19 "FD&C Act" means the Federal Food, Drug and Cosmetic Act, as the same may be amended or supplemented from time to time.

1.1.20 "FTO Status" means that (i) final Regulatory Approval (which includes without limitation WCH's consumer labeling and packaging) and, if applicable, Pricing Approval to market Product have been obtained, (ii) all legal claims, actions, proceedings and appeals with respect to a Product, including without limitation the Patent Litigations, have been finally resolved in WCH's and in IMPAX's favor or discontinued, and (iii) all relevant patents have expired, been declared invalid or determined by WCH not to be infringed by a Product.

1.1.21 "Good Clinical Practice" or "GCP" means the then current standards for clinical trials for pharmaceuticals, as set forth in the FD&C Act and applicable regulations promulgated thereunder, as amended from time to time, and such standards of good clinical practice as are required by the laws and regulations of the European Union and other Regulatory Authorities in countries in which Products are intended to be sold, to the extent such standards are not inconsistent with GCP under the FD&C Act.

1.1.22 "Good Laboratory Practice" or "GLP" means the then current standards for laboratory activities for pharmaceuticals, as set forth in the FD&C Act and applicable regulations promulgated thereunder, as amended from time to time, and such standards of good laboratory practice as are required by

the laws and regulations of the European Union and other Regulatory Authorities in countries in which Products are intended to be sold, to the extent such standards are not inconsistent with GLP under the FD&C Act.

1.1.23 "Good Manufacturing Practice" or "GMP" means the then current standards for the manufacture of pharmaceuticals, as set forth in the FD&C Act and applicable regulations promulgated thereunder, as amended from time to time, and such standards of good manufacturing practice as are required by the applicable laws and regulations of the European Union and other Regulatory Authorities in countries in which Products are intended to be sold, to the extent such standards are not inconsistent with GMP under the FD&C Act.

1.1.24 "++" means the ++ for Loratadine and Product provided in writing by WCH to IMPAX, as the same may be amended from time to time by the mutual written agreement of the Parties.

1.1.25 "++" means the ++ provided in writing by WCH to IMPAX, as the same may be amended from time to time by the mutual written agreement of the Parties.

1.1.26 "IMPAX Confidential Information" means all Technical Information pertaining to IMPAX's business or its Manufacturing operations disclosed by IMPAX to WCH hereunder. It is understood and agreed that nothing in this Agreement shall require IMPAX to disclose to WCH any of Schering Corporation's confidential information or any other confidential information or documentation that pertains solely to Schering Corporation and IMPAX hereby agrees not to disclose any such information to WCH.

1.1.27 "IMPAX Patents" shall mean those Patents owned or Controlled by IMPAX during the Term that claim a Product, its manufacture or method of use, including the Patents which are set forth on Exhibit A hereto.

1.1.28 "Indemnified Party" has the meaning set forth in Section 8.1.3.

1.1.29 "Indemnifying Party" has the meaning set forth in Section 8.1.3.

1.1.30 "Launch" means the date on which Product in the OTC Field is sold by WCH or one of its Affiliates for the first time to a Third Party for commercial distribution in a particular country in the Territory.

1.1.31 "Loratadine" means pharmaceutical active ingredient with the following chemical composition: ethyl 4-(8-chloro-5, 6-dihydro-11H-benzo [5,6] cyclohepta [1,2-b] pyridin-11-ylid-ene)-1 piperidinecarboxylate.

++ Confidential portions omitted and filed separately with the Commission.

1.1.32 "Manufacture," "Manufactured" or "Manufacturing" means all activities involved in the production of Products to be supplied to WCH or its Affiliates hereunder, including, without limitation, the preparation, formulation, finishing, testing, packaging, storage and labeling of Products and the handling, storage and disposal of any residues or wastes generated thereby.

1.1.33 "Materials" means all materials, including, without limitation, all raw materials, ingredients, packaging supplies and labels, required for the Manufacture of Products.

1.1.34 "Methods of Analysis" means the regulatory analytical test methods for the D-12 Product set forth in ANDA 76-050 and for the D-24 Product set forth in ANDA 75-989, as the same may be amended from time to time in accordance with the provisions of Section 5.3.

1.1.35 "NDA" means a New Drug Application, as defined in the FD&C Act, and applicable FDA rules and regulations.

1.1.36 "Net Sales" means the gross invoice price for Product sold by WCH or its Affiliates (or sublicensees pursuant to Section 2.1.2) to a Third Party customer less the reasonable and customary accrual-basis deductions from such gross amounts for: (i) normal and customary trade, cash and other discounts, allowances and credits actually allowed and taken directly with respect to sales of Product; (ii) credits or allowances actually granted for damaged goods, returns or rejections of Product; (iii) sales or similar taxes (including duties or other governmental charges levied on, absorbed or otherwise imposed directly on the sales of Product, including, without limitation, value added taxes or other governmental charges otherwise measured by the billing amount) which are included in billing amount; (iv) uncollectible accounts; (v) charge back payments and rebates granted to managed health care organizations or to federal, state and local governments, their agencies and purchasers and reimbursers or to trade customers, including but not limited to, wholesalers and chain and pharmacy buying groups; and (vi) rebates (or equivalents thereof) that are granted to or charged by national, state, provincial or local governmental authorities. Such amounts shall be determined from the books and records of WCH, its Affiliates and their respective sublicensees pursuant to Section 2.1.2 maintained in accordance with U.S. generally accepted accounting principles consistently applied. Sales between or among WCH, its Affiliates and its sublicensees pursuant to Section 2.1.2 shall be excluded from the computation of Net Sales if such Affiliates or sublicensees are not end-users, but Net Sales shall include the subsequent final sales to Third Parties by any such Affiliates or sublicensees.

1.1.37 "OTC Field" means the area of non-prescription (i.e., not requiring, by law or regulation, a prescription from a medical doctor) and/or over-the-counter sales for all human pharmaceutical uses.

1.1.38 "Party" means WCH or IMPAX or both, as the context requires.

1.1.39 "Patent Litigations" has the meaning set forth in Section 3.2.

1.1.40 "Patents" means all patents and patent applications, and all additions, divisions, continuations, continuations in-part, pipeline protection, substitutions, reissues, reexamination certificates, extensions, registrations, patent term extensions, supplementary protection certificates and renewals of any of the above.

1.1.41 "Person" means any natural person, corporation, general partnership, limited partnership, proprietorship, other business organization, trust, union, association or governmental authority.

1.1.42 "PPI Adjustment" has the meaning set forth in Section 6.3.2.

1.1.43 "Pricing Approval" means any approval for price or reimbursement as may be necessary or appropriate as a prerequisite for marketing any Product in the OTC Field in a particular country of the Territory.

1.1.44 "Product" means D-12 Product or D-24 Product or both, as the context requires.

1.1.45 "Pseudoephedrine" means the pharmaceutical active ingredient known as pseudoephedrine sulfate, USP.

1.1.46 "Recall" means any action by any Party to recover title to or possession of Product sold or shipped to Third Parties or the failure by a Party to sell or ship Product to Third Parties that would have been subject to recall if it had been sold or shipped.

1.1.47 "Regulatory Approval" means all authorizations by the competent Regulatory Authorities which are required for the manufacture, marketing, promotion, pricing, sale and use of a Product in a given country or regulatory jurisdiction in the Territory.

1.1.48 "Regulatory Authority" means any national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity involved in the granting of Regulatory Approval and/or Pricing Approval for Products in a country in the Territory.

1.1.49 "Regulatory Documents" means all regulatory submissions, correspondence, and written descriptions and written accounts of conversations, with Regulatory Authorities, Regulatory Approvals and Pricing Approvals.

1.1.50 "Related Infringement" has the meaning set forth in Section 11.2.1.

1.1.51 "Rolling Forecast" has the meaning set forth in Section 4.2.

1.1.52 "Seizure" means any action by FDA or any other Regulatory Authority to detain or destroy Product or prevent the release of Product.

1.1.53 "Semi-Exclusive Territory" means the countries of Japan and Korea; "semi-exclusive license" means that IMPAX may either Manufacture and sell Products for the OTC Field in its own name in each country in the Semi-Exclusive Territory or license one (1) other Person (other than WCH) in each country of the Semi-Exclusive Territory to make, have made, market, promote, use, distribute, sell, have sold, import and export Products for the OTC Field.

1.1.54 "Specifications" means the specifications for the D-12 Product set forth in ANDA 76-050 and for the D-24 Product set forth in ANDA 75-989, as the same may be amended from time to time in accordance with the provisions of Section 5.3.

1.1.55 "Technical Information" means (a) techniques and data, including ideas, inventions (including patentable inventions), practices, methods, knowledge, know-how, trade secrets, skill, experience, documents, apparatus, clinical and regulatory strategies, studies, test data, including pharmacological, toxicological and clinical test data (including bioequivalence studies), chemistry manufacturing and control data, analytical and quality control data, manufacturing, patent data or descriptions relating to any Product, and (b) chemical formulations, compositions of matter, product samples and assays relating to any Product.

1.1.56 "Term" has the meaning set forth in Section 9.1.

1.1.57 "Territory" shall mean both the Exclusive and Semi-Exclusive Territory.

1.1.58 "Third Party" means any Person other than WCH, IMPAX and their respective Affiliates.

1.1.59 "WCH Confidential Information" means all Technical Information and all information and data pertaining to WCH's business or products disclosed by WCH to IMPAX hereunder, including, without limitation, marketing and sales plans, artwork, formats, logos, drawings, customer lists and operating procedures and all ordering and sales information.

1.1.60 "\$" means United States dollars.

1.2 Construction of Certain Terms and Phrases. Unless the context of this Agreement otherwise requires, (i) words of any gender include each other gender; (ii) words using the singular or plural number also include the plural or singular number, respectively; (iii) the terms "hereof," "herein," "hereby" and derivative or similar words refer to this entire Agreement; (iv) the terms "Article" or "Section" refer to the specified Article or Section of this Agreement; and (v) Article and Section headings shall not affect the meaning or construction of any provision of this Agreement.

ARTICLE II
GRANT OF RIGHTS; EXCLUSIVITY

2.1 Grant of License.

2.1.1 IMPAX hereby grants to WCH an exclusive license within the Exclusive Territory and a semi-exclusive license within the Semi-Exclusive Territory, both with the right to grant sublicenses, under the IMPAX Patents and IMPAX's Technical Information and Regulatory Documents, to market, promote, use, distribute, sell, have sold, import and export Products for the OTC Field during the Term of this Agreement. WCH shall notify IMPAX in writing prior to having the name of any Third Party on a Product label. Notwithstanding the exclusive license set forth above, IMPAX shall be permitted to Manufacture and sell the D-12 Product to Schering Corporation in the United States, its territories and possessions.

2.1.2 IMPAX hereby grants WCH an exclusive license within the Exclusive Territory and a semi-exclusive license within the Semi-Exclusive Territory, both with the right to grant sublicenses, under the IMPAX Patents and IMPAX's Technical Information and Regulatory Documents, to make and have made Products for the OTC Field during the Term under the circumstances described in Section 2.2. IMPAX shall provide WCH with a hard copy of IMPAX's Technical Information, ANDA 76-050, ANDA 75-989 and Regulatory Documents relating to the Products and WCH shall have the right to file such Technical Information, ANDAs and Regulatory Documents with Regulatory Authorities, and reference the same in WCH's applications for Regulatory Approval, as necessary or advisable to obtain Regulatory Approval of Products. Upon WCH's request, IMPAX agrees to execute such further documents requested by WCH evidencing WCH's rights hereunder. The right to grant sublicenses of the rights granted under this Section 2.1.2 to Affiliates and Third Parties shall be upon IMPAX's prior written consent, which shall not be unreasonably withheld or delayed; provided however that any sublicensee under this Section 2.1.2 must agree in writing to be bound by WCH's obligations under this Agreement including but not limited to Article X and Section 6.2. Notwithstanding the exclusive license set forth above, IMPAX shall be permitted to grant Schering Corporation a license under the IMPAX Patents and IMPAX's Technical Information and Regulatory Documents to make and have made the D-12 Product in the United States, its territories and possessions.

2.2 Right to Manufacture. WCH shall have the right to manufacture Products pursuant to the license set forth in Section 2.1.2 at any time after (i) the fifth anniversary of the Launch of a Product in the United States by WCH upon six (6) months' prior written notice to IMPAX or (ii) IMPAX notifies WCH pursuant to the last sentence of Section 5.3.2 that a change required by the FDA or other Regulatory Authority creates an unreasonable burden on IMPAX or results in the continuing compliance by IMPAX with this Agreement uneconomical, so long as WCH is not in breach of this Agreement as of the date such notice is delivered. In such event, IMPAX shall furnish to WCH or its designee, on a non-exclusive basis, all Technical Information relating to the Manufacture of Products, including all manufacturing know-how, that is reasonably necessary to enable WCH to make and have made Products and provide all technical assistance, at WCH's cost, reasonably requested by WCH.

2.3 Exclusivity. During the Term, IMPAX and its Affiliates shall only sell Product for the OTC Field in the Exclusive Territory to WCH and shall not market, promote, use, distribute, sell, have sold, import, export, make or have made either a twelve-hour or twenty-four hour, extended release Loratadine and Pseudoephedrine combination product (other than the Products) which is, in dosage strength, identical to either Product (a "Competing Product") to a Third Party for the OTC Field in the Exclusive Territory. Notwithstanding the foregoing, IMPAX shall be permitted (i) to Manufacture and sell D-12 Product to Schering Corporation in the United States, its territories and possessions; and (ii) to market, promote, use, distribute, sell, have sold, import, export, make or have made a Competing Product that IMPAX or its Affiliate acquires through an acquisition, divestiture, merger, joint venture or other business combination, provided that such Competing Product did not account for more than seventy percent (70%) of the sales of the business acquired by IMPAX or its Affiliate in such transaction during the twelve (12) month period immediately preceding the consummation of such transaction.

2.4 Non-Compete. During the Term, neither WCH nor its Affiliates shall market, promote, use, distribute, sell, have sold, import, export, make or have made a Competing Product for the OTC Field in the Territory. Notwithstanding the foregoing, WCH and its Affiliates shall be permitted to market, promote, use, distribute, sell, have sold, import, export, make or have made a Competing Product acquired by WCH or its Affiliates through an acquisition, divestiture, merger, joint venture or other business combination, provided that such Competing Product did not account for more than seventy percent (70%) of the sales of the business acquired by WCH or its Affiliate in such transaction during the twelve (12) month period immediately preceding the consummation of such transaction.

2.5 IMPAX Patents. IMPAX shall be responsible, at its cost and expense, for prosecuting to issuance all patent applications within the IMPAX Patents, for filing and prosecuting all patent reissues and re-examinations, for applying for and obtaining any available patent term extensions and supplementary protection certificates, and for paying all maintenance fees, on a large-entity basis, on all patent applications and patents which constitute IMPAX Patents under this Agreement.

2.6 Reservation of Rights. All rights under the IMPAX Patents, IMPAX's Technical Information, IMPAX Confidential Information and IMPAX's Regulatory Documents not expressly granted herein to WCH are reserved to IMPAX.

ARTICLE III DEVELOPMENT ACTIVITIES AND PATENT LITIGATION

3.1 Development and Registration Responsibilities.

3.1.1 Prior to the Effective Date IMPAX has performed the following development and registration activities:

(i) designed, conducted and met all bioequivalency test requirements for Regulatory Approval by FDA in accordance with FDA guidance documents;

(ii) designed and conducted all dosage form, formulation, process, and chemistry manufacturing and control ("CMC") and related technical studies on Products, including preparation of dosage form CMC regulatory documents required for FDA review and approval of the Products; and

(iii) FDA acceptance for filing of ANDA No. 76-050 and ANDA No. 75-989 with FDA seeking approval of the D-12 Product and D-24 Product, respectively, as generic prescription drugs and is prepared for FDA's pre-approved inspection.

3.1.2 At WCH's request, IMPAX shall supplement and/or amend ANDA No. 76-050 and ANDA No. 75-989 to include WCH's consumer labeling and packaging and any other documentation necessary or advisable to support WCH's consumer labeling and packaging for the OTC Field for the Products. IMPAX shall, at its expense, (i) complete the construction, installation, commissioning, IQ, OQ and PQ of all Facilities and all equipment necessary for Manufacture of Products and (ii) conduct all scale up and validation activities for FDA approval of Products.

3.1.3 IMPAX shall own and maintain ANDA No. 76-050 and ANDA No. 75-989 and shall use its Commercially Reasonable Efforts to pursue, and at its expense perform any additional development activities to obtain, final FDA approval of these ANDAs for the OTC Field. WCH may submit applications for Regulatory Approval for Products in the Territory as it deems advisable (including NDAs); provided that WCH shall not be required to make any such submissions for Regulatory Approval unless it determines to do so in its sole discretion. Except for ANDA No. 76-050 and ANDA No. 75-989, WCH shall file, own and maintain all other submissions for Regulatory Approval and Pricing Approval of Products for the OTC Field in the Exclusive Territory. IMPAX shall be responsible for providing the CMC and related technical components of such submissions, as jointly determined by the Parties. Upon WCH's request and at WCH's cost, IMPAX shall use Commercially Reasonable Efforts to provide additional registration batches (including stability and analytical testing) and required documentation to support any NDA that WCH may submit in the United States. WCH shall bear the full cost of any additional studies required for Regulatory Approval of the Products outside of the United States. To the extent that IMPAX undertakes any additional development work which is not required for FDA approval of a Product, at WCH's written request, to support Regulatory Approval in the Territory outside the United States, WCH shall reimburse IMPAX for the Direct Development Cost thereof.

3.1.4 The Parties shall cooperate with, and assist, each other in connection with their activities hereunder including without limitation the protocol for scale up and validation and addressing regulatory questions, and preparing updates and supplements to regulatory filings for Product for the OTC Field in the Territory. IMPAX shall be responsible for all communications with

FDA regarding ANDA No. 76-050 and ANDA No. 75-989. WCH shall be responsible for all communications with the FDA and other Regulatory Authorities regarding applications for Regulatory Approval submitted by WCH and post-Regulatory Approval regulatory requirements for Product marketed by WCH for the OTC Field in the Territory, including pharmacovigilance and Adverse Drug Experience reporting, unless otherwise agreed in advance in writing by the Parties.

3.1.5 Each Party represents that it has complied and shall comply with all applicable GLP, GCP and GMP in the conduct of the development activity performed by it for the Products.

3.1.6 Upon WCH's request, IMPAX shall use Commercially Reasonable Efforts to eliminate animal derived materials from the Products and WCH shall reimburse IMPAX for the actual costs incurred by IMPAX (provided that such are approved in writing by WCH prior to being incurred by IMPAX) in connection therewith.

3.2 Patent Litigations. Schering Corporation ("Schering") has instituted lawsuits against IMPAX for patent infringement with respect to the D-12 Product and the D-24 Product. In Schering Corp. v. IMPAX Laboratories, Inc., Civil Action No. 01-0520 (D.N.J.), Schering has charged infringement of U.S. Patent 4,659,716 (the "'716 patent") with respect to the D-12 Product. In Schering Corp. v. IMPAX Laboratories, Inc., Civil Action No. 01-0009 (D.N.J.), Schering has charged infringement of both the '716 patent and U.S. Patent 5,314,697 (the "'697 patent") with respect to the D-24 Product (collectively, Civil Action No. 01-0520 (D.N.J.) and Civil Action No. 01-0009 (D.N.J.), are referred to herein as the "Patent Litigations"). Schering has also alleged in both actions that it may be necessary in the future to expand the actions to include claims for infringement of U.S. Patent 4,863,931 (the "'931 patent"). Both of these cases have been consolidated, for pretrial purposes, with other patent infringement actions that Schering has filed against other defendants, with this consolidated action identified as Schering Corp. v. Geneva Pharmaceuticals, Inc., Civil Action Nos. 98-1259 (JAG)(GDH); 99-2237 (JAG)(GDH); 00-0255 (JAG)(GDH); 99-2820 (JAG)(GDH); 00-1439 (JAG)(GDH); 00-1657 (JAG)(GDH); 00-2944 (JAG)(GDH); 01-0009 (JAG)(GDH); 01-0279 (JAG)(GDH); 01-0520 (JAG)(GDH); and 02-0328 (JAG)(GDH). IMPAX agrees to diligently defend the allegations against it in the Patent Litigations and to use all reasonable efforts to have the '716 and '697 patents (and also the '931 patent, to the extent any claims are made in the future of infringement of the '931 patent) declared invalid, unenforceable and/or not infringed by the D-12 Product and D-24 Product, including, but not limited to, by defending all appeals by Schering, and by filing and diligently prosecuting all reasonable appeals of any ruling or decision adverse to IMPAX. WCH agrees to reasonably cooperate with IMPAX in the conduct of the Patent Litigations and other proceedings involving WCH. All liabilities, damages attorneys fees and other costs and expenses incurred in connection with defending the Patent Litigations (including any claim of infringement of the '931 patent) and defending and prosecuting all related appeals shall be borne by IMPAX. IMPAX shall keep WCH promptly informed of any material developments and shall from time to time consult with WCH regarding the status of the Patent Litigations and shall provide WCH with copies of all documents, not containing Schering's confidential information, which are filed in, and all unprivileged written communications relating to the Patent

Litigations. Notwithstanding anything to the contrary in this Agreement but subject to the next sentence, IMPAX shall have no obligation to supply either Product to WCH prior to the earlier of (i) a United States District Court decision that claims 1 and 3 of the '716 Patent are either invalid, unenforceable or not infringed by such Product or (ii) October 21, 2004 and IMPAX shall have no obligation to supply the D-24 Product to WCH prior to the earlier of (i) a United States District Court decision that the '697 Patent is either invalid, unenforceable or not infringed by the D-24 Product or (ii) April 23, 2013, unless after July 25, 2003 WCH provides IMPAX with an indemnity agreement acceptable to IMPAX for any damages assessed against IMPAX for infringement of such Patent prior to the occurrence of the first of such events, such acceptance by IMPAX not to be unreasonably withheld or delayed. The foregoing shall not relieve IMPAX of its obligation to supply WCH with Product solely for uses reasonably related to the development and submission of information under the FD&C Act.

3.3 Joint Defense Agreement. Promptly following the Effective Date, the Parties shall enter into a joint defense agreement mutually acceptable to both Parties containing customary terms and conditions for the purpose of, among other things, preserving confidentiality and any applicable privilege attaching to information and data exchanged by the Parties and pursuant to this Agreement. IMPAX agrees to provide to WCH pursuant to the joint defense agreement a copy of the written opinion of IMPAX's outside counsel, with copies of all documents referenced in said opinion, regarding the validity or invalidity of ++ U.S. Patent ++.

3.4 Product Launch. WCH shall not be required to Launch Products in any country unless it determines, in its sole discretion, to do so. If WCH does not, subject to supply by IMPAX of launch quantities of such Product pursuant to the forecasts set forth in Section 4.2, use Commercially Reasonable Efforts to Launch a Product in the OTC Field (i) in the United States within three (3) months, or (ii) in the another country in the Territory within five (5) months, following such Product having FTO Status for the OTC Field in such country, then IMPAX, at its option and as its sole and exclusive remedy, may, upon written notice to WCH, convert the licenses granted hereunder in such country for such Product under the IMPAX Patents and Technical Information to non-exclusive licenses (and thereby remove the restrictions placed on IMPAX in Section 2.3 for such Product in such country) unless within thirty (30) days after such written notice WCH Launches Product in the OTC Field in such country. Following the Launch of a Product in any country of the Territory, WCH shall use Commercially Reasonable Efforts to market such Product in such country; provided that nothing shall require WCH to continue marketing a Product in a country if WCH determines, in its sole judgment, that such Product may be subject to a regulatory or other legal action or infringe any intellectual property right of any Third Party in such country. WCH shall promptly notify IMPAX in writing of such discontinuance. If within thirty (30) days after receipt of IMPAX's written request, WCH does not resume marketing such Product in such country, then IMPAX, at its option and as its sole and exclusive remedy, may, upon written notice to WCH, convert the licenses granted hereunder in such country for such Product under the IMPAX Patents and Technical Information to non-exclusive licenses (and thereby remove the restrictions placed on IMPAX in Section 2.3 for such

++ Confidential portions omitted and filed separately with the Commission.

Product in such country). If at anytime after Launch of a Product in a country, IMPAX reasonably believes that WCH is not using Commercially Reasonable Efforts to market such Product in such country, then IMPAX shall notify WCH and if WCH does not begin to use Commercially Reasonable Efforts to market such Product within such country within thirty (30) days after such written notice, then IMPAX, at its option and as its sole and exclusive remedy, may, upon written notice to WCH, convert the licenses granted hereunder in such country for such Product under the IMPAX Patents and Technical Information to non-exclusive licenses (and thereby remove the restrictions placed on IMPAX in Section 2.3 for such Product in such country).

ARTICLE IV SUPPLY

4.1 Supply. During the Term, WCH shall order from IMPAX, subject to WCH's right to Manufacture Products set forth in Section 2.2, WCH's requirements of Products for the OTC Field in the Territory and IMPAX shall Manufacture and deliver Products to WCH, subject to (i) WCH having complied with its obligation to provide Rolling Forecasts pursuant to Section 4.2 and (ii) IMPAX's ability to source active ingredient (provided that IMPAX has used Commercially Reasonable Efforts to do so) in the event that such ability is impaired by WCH's refusal to approve, or withdrawal of approval for, a supplier of active ingredient, in such quantities, in such packaging and at such times as ordered by WCH. IMPAX shall maintain the resources necessary to Manufacture Products at the Facility and shall provide, at its own expense, all equipment, Materials and labor necessary to do so. If IMPAX's Manufacturing obligations for all products that use the same equipment and resources at the Facility as the Products exceed eighty five percent (85%) of its total capacity for such equipment and resources at the Facility for more than thirty (30) consecutive days, IMPAX shall notify WCH in writing and, upon WCH's request, IMPAX shall use Commercially Reasonable Efforts to increase its Manufacturing capacity at the Facility to maintain a better than eighty five percent (85%) ratio. If any batch of Loratadine or Product fails to meet the ++based on the ++ performed pursuant to Section 5.2, the Parties shall be relieved of their respective obligations to supply and accept delivery of Product relating to said failed batch.

4.2. Forecasts. At least four and one-half (4 1/2) months prior to the anticipated Launch date (provided that the anticipated Launch date shall be at least four and one-half (4 1/2) months after the date on which WCH provides IMPAX with the ++ or notifies IMPAX in writing that none are required) in each country of the Territory, WCH shall submit to IMPAX a forecast of the quantity of Product that WCH anticipates ordering from IMPAX for such country during the twelve (12) month period (broken down by Product and by month) following Launch and every month thereafter at least three (3) months prior to the beginning of the period covered by the forecast WCH shall update such forecast on a rolling twelve (12) months basis (each, a "Rolling Forecast"). WCH shall place purchase orders pursuant to Section 4.3 for at least the quantity of Product

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specified in the first three (3) months of each such Rolling Forecast and the remaining nine (9) months shall be a non-binding estimate prepared by WCH using Commercially Reasonable Efforts. Except as set forth in the immediately preceding sentence, WCH shall not be required to order any fixed minimum quantity of Product, notwithstanding any forecast or prior course of dealing. If WCH fails to give IMPAX Rolling Forecasts as specified above after notice by IMPAX of such failure the prior three (3) months Rolling Forecast shall apply. IMPAX shall use Commercially Reasonable Efforts to allocate capacity at the Facility to WCH so that it can supply WCH with ++ tablets of D-12 Product per calendar month and ++ tablets of the D-24 Product per calendar month.

4.3 Orders and Delivery. WCH shall place its firm orders for Products with IMPAX by submitting a purchase order which sets forth (i) the quantity of Product ordered for delivery; and (ii) the delivery date for that order. Unless IMPAX notifies WCH in writing within fifteen (15) days of receipt of a purchase order that it is unable to deliver Products in accordance with such purchase order, IMPAX shall be deemed to have accepted such purchase order as a binding order. If IMPAX notifies WCH that it is unable to fill such purchase order, it shall indicate the portion of such purchase order IMPAX cannot supply by the requested delivery date and specify alternate delivery dates. WCH may cancel any firm purchase order (in whole or in part) at any time prior to the delivery for any quantity of Product; provided that, except in the event that this Agreement is being terminated by WCH pursuant to Section 9.2, 9.3.3 or 9.3.4 or by IMPAX pursuant to Section 5.3.2 or 9.2.3, (i) if IMPAX has completed the Manufacture of Products pursuant to such firm purchase order, WCH shall pay the price therefor and (ii) if IMPAX has commenced but not completed the Manufacture of Product pursuant to such firm purchase order, WCH shall reimburse IMPAX for Material and labor costs in respect of any works-in-progress or Materials orders pursuant to such cancelled purchase order (or part thereof) at the time notice of cancellation is received by IMPAX. All Products shall be delivered F.O.B. the Facility in accordance with WCH's instructions. Time is of the essence for all deliveries of Products.

4.4 Manufacturing Date. IMPAX shall schedule its Manufacturing operations so that all Products delivered have the maximum shelf life reasonably possible and in any event no Product delivered hereunder shall have less than expiry less two (2) months of shelf life (unless a longer period of time is agreed to by the Parties), based on the dating included on such Products' packaging, remaining at the time of delivery.

4.5 Inconsistent Terms and Conditions. The terms and conditions of any invoice, acknowledgement or similar document provided by IMPAX for Products, or any terms and conditions of purchase orders provided by WCH for Products, which are inconsistent with or in addition to the terms of this Agreement, shall be null and void.

++ Confidential portions omitted and filed separately with the Commission.

ARTICLE V
COMPLIANCE, QUALITY AND ENVIRONMENTAL

5.1 Compliance with Law. IMPAX and, if WCH is Manufacturing Product pursuant to Section 2.2, WCH shall conduct its Manufacturing operations hereunder in a safe and prudent manner, in compliance with all applicable laws and regulations (including, but not limited to, those dealing with occupational safety and health, those dealing with public safety and health, those dealing with protecting the environment, and those dealing with disposal of wastes), and in compliance with all applicable provisions of this Agreement. IMPAX and, if WCH is Manufacturing Product pursuant to Section 2.2, WCH shall obtain all necessary registrations and permits pertaining to activities contemplated by this Agreement. To the extent necessary for the Regulatory Approval of Products, IMPAX and, if WCH is Manufacturing Product pursuant to Section 2.2, WCH shall permit the inspection of its premises by Regulatory Authorities and shall supply all documentation and information to obtain or maintain Regulatory Approval of Products.

5.2 Manufacturing Quality. IMPAX shall obtain all Materials from WCH approved suppliers. All Products shall be Manufactured at the Facility and in accordance with GMPs. IMPAX shall sample and analyze all Materials upon receipt to ensure that such Materials are free of defects and meet the applicable specifications therefor. Until WCH notifies IMPAX in writing that such practice may be suspended or discontinued, IMPAX shall provide samples from each batch of Loratadine to be used in the Manufacture of any Product and samples from each Batch of Product to ++ (or such other contract laboratory specified by WCH) to perform the ++ to ensure that such Loratadine and Product, as the case may be, meet the ++. IMPAX shall promptly provide WCH with the results of such ++. ++ (or such other laboratory specified by WCH) shall bill WCH directly for such services, and such amounts shall not be included in Direct Manufacturing Cost. IMPAX shall not use any Loratadine in the Manufacture of Product that does not meet the ++ and shall not ship any Product to WCH that does not meet the ++. IMPAX shall take all necessary steps to prevent contamination and cross contamination of Products. Products shall be unadulterated (within the meaning of the FD&C Act) and free from contamination, diluents and foreign matter in any amount. IMPAX shall perform the quality control tests with respect to Products in accordance with the Methods of Analysis, the cost of the same to be included in the price hereinafter specified. IMPAX shall promptly, upon completion of such tests, deliver to WCH a copy of the record of such tests performed on, and a Certificate of Analysis for, each Batch of Product. At WCH's request, IMPAX shall deliver a representative sample (in the same amount as the sample that IMPAX retains for its own purposes) from each Batch of Product to WCH's designated representative. On the Effective Date or promptly thereafter, the Parties shall execute and deliver to each other the Quality Agreement substantially in the form of Exhibit C. Each Party agrees to perform its respective obligations under the Quality Agreement in accordance with such agreement.

++ Confidential portions omitted and filed separately with the Commission.

5.3 Manufacturing Changes.

5.3.1 IMPAX shall not make any changes to the Manufacturing process, the Manufacturing equipment, the Specifications, the Materials, the sources of Materials or the Methods of Analysis without the prior written consent of WCH, which consent shall not be unreasonably withheld. If either Party requests in writing a change in the Manufacturing process, the Manufacturing equipment, the Specifications, the Materials, the source of Materials or Methods of Analysis with respect to any Product that is not the result of a requirement of FDA or any other Regulatory Authority, the other Party shall use Commercially Reasonable Efforts to make or accept such change, as the case may be. The requesting Party shall provide the other Party with a detailed written report of all proposed changes to the Manufacturing process, the Manufacturing equipment, the Specifications, the Materials, the sources of Materials or the Methods of Analysis.

5.3.2 If FDA or any other Regulatory Authority requests or requires any change in the Manufacturing process, the Manufacturing equipment, the Specifications, the Materials, the source of Materials or Methods of Analysis with respect to any Product the Parties shall meet and discuss an implementation plan for such change and use all Commercially Reasonable Efforts to accommodate such change to meet the FDA's or such other Regulatory Authority's requirements. Each Party will bear its respective costs associated with, or incurred as a result of, such change. Each Party agrees to promptly forward to the other copies of any written communication received by such Party from the FDA or any other Regulatory Authority that may affect the Manufacture or supply of any Product as contemplated herein. Notwithstanding the foregoing, if after Launch of the D-12 Product IMPAX determines, in the exercise of its reasonable judgment, that a change required by the FDA or other Regulatory Authority creates an unreasonable burden on IMPAX or results in the continuing compliance by IMPAX with this Agreement uneconomical and if, upon IMPAX's request, WCH does not agree (i) to pay the incremental cost of complying with the changes required by FDA or such other Regulatory Authority (which costs shall not be included in Direct Manufacturing Costs hereunder to the extent paid by WCH), or (ii) to exercise its right to Manufacture pursuant to Section 2.2, then IMPAX may by notice in writing to WCH, given no later than thirty (30) days after such refusal by WCH, terminate this Agreement.

5.4 Testing by WCH. WCH may test the Product samples in accordance with the applicable Methods of Analysis. If the analysis of any Product performed by or for WCH differs from IMPAX's analysis of the same Batch, WCH shall advise IMPAX and IMPAX and WCH agree to consult with each other in order to explain and resolve the discrepancy between each other's determination. If, after a good faith attempt by the Parties to do so, such consultation does not resolve the discrepancy, an independent, reputable laboratory designated by WCH and reasonably acceptable to IMPAX (such acceptance not to be unreasonably withheld or delayed) shall repeat the applicable Methods of Analysis on representative samples from such Batch provided by or for WCH. The costs of the independent laboratory referred to above shall be borne by (i) WCH if such laboratory determines that the Product conforms to the Specifications or (ii) IMPAX if such laboratory determines that the Product does not conform to the Specifications. If so requested by WCH in writing, IMPAX shall promptly send a new Batch of Product (of similar quantity as to the amount of such Product being

analyzed as set forth above) to WCH. WCH shall not be obligated to pay for any Product (and if WCH has paid for such Product IMPAX shall promptly reimburse WCH) that such laboratory determines that does not conform to the Specifications, but shall be obligated to pay for any new Batch of Product which conforms to the Specifications that is sent as specified above, except that IMPAX shall pay all transportation costs for such replacement Batch. If WCH shall reject any Batch of Product, IMPAX's only obligation and liability to WCH shall be to replace the rejected Batch of Product.

5.5 Samples and Record Retention. IMPAX shall retain records and retention samples of each Batch of Product for at least thirty-six (36) months after the expiration date of that Batch and shall make the same available to WCH upon request. Retention samples shall only be destroyed after the required holding period and then only after notice to WCH. During and after the Term, IMPAX shall assist WCH with respect to any complaint, issue or investigation relating to Product.

5.6 Inspection.

5.6.1 IMPAX shall give access to representatives of WCH, at all reasonable times and upon reasonable notice during regular business hours, to the Facility and any other facility in which Products are Manufactured, tested and/or stored, and to all Manufacturing records with respect to Products for the purpose of inspection. WCH shall have the right while at any such Facility to inspect IMPAX's records, permits, and licenses to evaluate work practices and compliance with all applicable FDA and other Regulatory Authority laws and regulations, occupational health and safety, and environmental laws and regulations, controlled substances laws and regulations, GMP and warehousing practices and procedures. Upon WCH's request, IMPAX shall provide copies of Batch records, quality control, quality assurance and validation documents reasonably relating to the Product. Notwithstanding any inspection performed by WCH, IMPAX shall remain solely responsible for operating its Facilities and for complying with its obligations under this Agreement. Neither the rights granted to WCH pursuant to this Section 5.6.1, nor any inspection performance by WCH, shall impose any liability on WCH, except in the case of gross negligence or willful misconduct on the part of WCH.

5.6.2 At any time during which WCH is Manufacturing Product pursuant to Section 2.2, WCH shall give access to representatives of IMPAX, at all reasonable times and upon reasonable notice during regular business hours, to the facility in which Products are Manufactured, tested and/or stored, and to all Manufacturing records with respect to Products, for the purpose of inspection. IMPAX shall have the right while at any such facility to inspect WCH's records, permits, and licenses to evaluate work practices and compliance with all applicable FDA and other Regulatory Authority laws and regulations, occupational health and safety, and environmental laws and regulations, controlled substances laws and regulations, GMP and warehousing practices and procedures. Upon IMPAX's request, WCH shall provide copies of Batch records, quality control, quality assurance and validation documents reasonably related to the Product. Notwithstanding any inspection performed by IMPAX, WCH shall remain solely responsible for operating its facilities and for complying with its obligations under this Agreement. Neither the rights granted to IMPAX pursuant to this Section 5.6.2, nor any inspection performance by IMPAX, shall impose any liability on IMPAX, except in the case of gross negligence or willful misconduct on the part of IMPAX.

5.7 Adverse Drug Experience Reporting. Each Party shall fully, accurately and promptly provide to the other Party with all data known to it at any time during the term of this Agreement or thereafter, which data indicate that any Product marketed by WCH is or may be unsafe, lacks utility, or otherwise does not meet Specifications in accordance with the Adverse Event Reporting Procedures set forth in Exhibit D attached hereto (as the same may be amended from time to time by notice in writing from WCH to IMPAX). WCH shall determine whether such information is required to be reported and report the same as required, to FDA and any other Regulatory Authority.

5.8 Recalls and Seizure. Each Party shall keep the other Party promptly and fully informed of any notification or other information whether received directly or indirectly which might result in the Recall or Seizure of Product. If either Party determines that it is necessary to Recall any Product, it shall immediately notify the other Party. Prior to commencing any Recall, the Parties shall review with one another the manner in which the Recall is to be carried out and any instructions or suggestions of the applicable Regulatory Authorities. IMPAX and WCH shall effect the Recall in the manner agreed upon between the Parties in as expeditious a manner as possible and in such a way as to cause the least disruption to the sales of any Products and to preserve the goodwill and reputation associated with the Products and each Party. In any such situation, WCH shall have the right to make all final decisions regarding such Recall of the Products marketed by WCH.

5.9 Environmental, Occupational Health and Safety. IMPAX shall report to WCH, and, if WCH is Manufacturing Product pursuant to Section 2.2, WCH shall report to IMPAX, as soon as possible after any of the following incidents related to the Manufacturing operations hereunder occurs:

- (i) significant injuries or occupational illness;
- (ii) property damage in excess of \$50,000;
- (iii) inspections by any environmental protection agency or occupational health and safety agency; or
- (iv) requests for information, notices of violations or other significant governmental and safety agency communications relating to environmental, occupational health and safety compliance.

IMPAX shall only use waste haulers, brokers and disposal sites which WCH has approved in writing for hazardous waste generated by the Manufacturing operations, such approval not to be unreasonably withheld or delayed. IMPAX shall have title to and be responsible for disposing in an environmentally safe manner all residue and waste resulting from the Manufacturing operations performed by it hereunder. IMPAX shall not use WCH trademarks or trade dress to identify any waste materials or residues.

At any time during which WCH is Manufacturing Product pursuant to Section 2.2, WCH shall only use waste haulers, brokers and disposal sites which IMPAX has approved in writing for hazardous waste generated by the Manufacturing operations, such approval not to be unreasonably withheld or delayed. WCH shall have title to and be responsible for disposing in an environmentally safe manner all residue and waste resulting from the Manufacturing operations performed by it hereunder.

ARTICLE VI
LICENSE PAYMENTS, ROYALTIES, AND SUPPLY PRICE

6.1 License Payments. Subject to Section 9.3.3, WCH shall make the following non-refundable license payments to IMPAX which shall be due and payable one (1) time only and within thirty (30) days after the occurrence of the corresponding event set forth below (provided that with respect to the Product to which the event relates all prior events in the list involving such Product have occurred; and provided further that this Agreement is in effect with respect to the Product to which the event relates at the time of the occurrence of such event and that notice of termination shall not have been given pursuant to Section 9.3.2 with respect to the Product to which the event relates prior to the occurrence of such event):

	Event -----	Payment -----
(i)	The Effective Date of this Agreement	\$++
(ii)	Placement on stability of a D-12 Product pilot batch in WCH's consumer blister packaging	\$++
(iii)	Placement on stability of a D-24 Product pilot batch in WCH's consumer blister packaging	\$++

++ Confidential portions omitted and filed separately with the Commission.

	Event -----	Payment -----
(iv)	Filing with FDA an ANDA supplement/amendment for D-12 Product to support 24 month expiry based on stability studies in WCH's consumer blister packaging	\$++
(v)	Filing with FDA an ANDA supplement/amendment for D-24 Product to support 24 month expiry based on stability studies in WCH's consumer blister packaging	\$++
(vi)	WCH's acceptance of successful scale-up and validation (based on WCH's approval of final validation report) of D-12 Product	\$++
(vii)	WCH's acceptance of successful scale-up and validation (based on WCH's approval of final validation report) of D-24 Product	\$++
(viii)	The later to occur of (a) January 1, 2003 or (b) final D-12 Product ANDA approval by FDA with WCH's consumer labeling and blister packaging	\$++
(ix)	The later to occur of (a) January 1, 2003 or (b) final D-24 Product ANDA approval by FDA with WCH's consumer labeling and blister packaging	\$++
(x)	The later to occur of (a) January 1, 2003 or (b) Launch of the D-12 Product by WCH in the United States	\$++
(xi)	The later to occur of (a) January 1, 2003 or (b) Launch of the D-24 Product by WCH in the United States	\$++

++ Confidential portions omitted and filed separately with the Commission.

6.2 Royalties.

6.2.1 During the Term following the date of Launch of each Product in a country of the Territory through the later of five (5) years from Launch in such country and the expiration of the last to expire issued IMPAX Patent in such country, if any, WCH shall pay to IMPAX, on a quarterly basis, a royalty of ++ percent (++) on Net Sales of such Product (whether or not Manufactured by IMPAX, WCH pursuant to Section 2.2 or WCH's sublicensees pursuant to Section 2.1.2) sold for the OTC Field on a country-by-country basis in the Territory during the previous quarter.

6.2.2 During any period and for each country that royalties are due and payable pursuant to Section 6.2.1, WCH shall, within thirty (30) days after each calendar quarter for sales of Product for the OTC Field in the United States and within sixty (60) days after each calendar quarter for sales of Product for the OTC Field within the Territory outside the United States, furnish to IMPAX a written quarterly report showing (i) the Net Sales of Product for the OTC Field sold by WCH and its Affiliates and sublicensees pursuant to Section 2.1.2 during the reporting period in such country; (ii) the royalties which shall have accrued hereunder in respect of such sales in such country; (iii) withholding taxes, if any, required by law to be deducted in respect of such royalty payments; and (iv) the exchange rates used in determining the amount of payment hereunder.

6.2.3 Payments accrued in each quarter shall be paid to IMPAX no later than thirty (30) days after the end of such quarter for the United States and no later than sixty (60) days after the end of such quarter for all other countries. Any amounts not paid within thirty (30) days after the due date thereof shall bear interest at the rate equal to eighteen percent (18%) per annum.

6.2.4 All royalty payments to be made pursuant to this Agreement shall be made in \$. Amounts based on Net Sales in currencies other than \$ shall be converted to \$ at the WCH financial statement exchange rate applied by WCH on a consistent basis in WCH's own financial accounting on the date such payment is due.

6.3 Supply Price.

6.3.1 IMPAX shall invoice WCH for the prices set forth in Exhibit B attached hereto, subject to adjustment as set forth in Sections 6.3.2, 6.3.3 and 6.3.4, for all Products delivered to WCH hereunder. All prices are inclusive of taxes, shipping costs to the point of delivery, customs duties and other charges.

++ Confidential portions omitted and filed separately with the Commission.

6.3.2 The Direct Manufacturing Cost, and the quality control, Materials, labor and overhead components thereof, as of June 1, 2002 which formed the basis of the price for each Product are set forth on Exhibit B attached hereto. IMPAX shall use Commercially Reasonable Efforts to minimize the Direct Manufacturing Cost of each Product. Commencing with June 1, 2003 and each December 1st and June 1st thereafter (in each case, an "Adjustment Date"), IMPAX may propose an adjustment to the prices to reflect documented changes in Direct Manufacturing Cost per unit of Product on such June 1st or December 1st, as the case may be, as compared to the Direct Manufacturing Cost per unit of Product on June 1, 2002 for the first adjustment and thereafter on the immediately preceding June 1st or December 1st, as the case may be, (without regard to intervening fluctuations); provided that IMPAX gives WCH not less than ninety (90) days' prior written notice of any proposed price increase and that IMPAX may not increase the price of a Product more than once during any Contract Year; and provided, further, that any such increase shall not exceed the relevant PPI Adjustment. If WCH does not accept IMPAX's proposed price increases, the Parties shall negotiate in good faith. If the Parties conclude their negotiations and agree upon Product prices, such agreed upon price increases shall be effective as of the expiration of such ninety (90) day notice period. In the event that the Parties are unable to agree during the negotiations described above, this Agreement shall be automatically terminated effective six (6) months after the expiration of such ninety (90) day notice period. Until the date of such termination, IMPAX shall supply WCH such Products at the prices then in effect without such price increase. "PPI Adjustment" means the amount calculated in accordance with the following formula:

DMC x PPI - BPPI BPPI

Where,
DMC = Direct Manufacturing Cost on June 1, 2002 for the first adjustment and thereafter on the Adjustment Date immediately preceding the Adjustment Date in question;

BPPI = the Bureau of Labor Statistics Producer's Price Index for Pharmaceutical Preparations (Code 2834) on June 1, 2002 for the first adjustment and thereafter on the Adjustment Date immediately preceding the Adjustment Date in question; and

PPI = the Bureau of Labor Statistics Producer's Price Index for Pharmaceutical Preparations (Code 2834) on the Adjustment Date in question.

6.3.3 Continuous improvement initiatives, mutually agreeable

to the Parties shall be established to provide for continuous cost reductions during the Term of this Agreement. Continuous improvement teams consisting of equal representation from each Party shall use reasonable efforts to work to identify and implement cost savings at a targeted rate of five percent (5%) of WCH's purchase price per Contract Year, but the foregoing shall not constitute a guarantee by IMPAX of any cost reductions. Any documented savings shall be allocated to the Parties in proportion to the level of contribution by each Party to realize the savings. Any cost savings allocated to WCH shall be in the form of reduced purchase price.

6.3.4 Notwithstanding any provision herein to the contrary, if at any time IMPAX makes sales of any Product to any person in any country of the Territory at a price lower than the price then in effect hereunder for such Product, such lower price shall be made available to WCH hereunder, with respect to WCH's inventory of Product in such country as well as future purchases of Product for resale in such country, for so long as IMPAX continues to make sales to such person at such lower price.

6.3.5 WCH shall pay invoices for Products delivered hereunder in \$ not later than thirty (30) days after the later of receipt of Products covered by such invoice and receipt of such invoice. In addition to its other rights and remedies, IMPAX shall have the right to assess interest on amounts past due by more than fifteen (15) days at the rate of one and one-half percent (1 1/2%) per month, or the highest rate permissible by law, if lower.

6.4 Withholdings. Any and all income or similar taxes imposed or levied on account of the receipt of payments under this Agreement which are required to be withheld shall be paid by WCH on behalf of IMPAX and shall be paid to the proper taxing authority. Proof of payment shall be secured, if available, and sent to IMPAX by WCH as evidence of such payment in such form as required by the tax authorities having jurisdiction over WCH. Such taxes shall be deducted from the payments that would otherwise be remittable by WCH.

6.5 Audit Rights. WCH shall have the right, at its own expense, through its independent certified public accountant (reasonably acceptable to IMPAX) to access the books and records of IMPAX and its Affiliates, as may be reasonably necessary, to verify the accuracy of IMPAX's Direct Development Costs and Direct Manufacturing Costs. IMPAX shall have the right, at its own expense, through its independent certified public accountant (reasonably acceptable to WCH) to access the books and records of WCH and its Affiliates, as may be reasonably necessary, to verify the accuracy of WCH's Net Sales. Such access shall be conducted after thirty (30) days' prior written notice to the Party being audited and during ordinary business hours and shall not be more frequent than once per Contract Year or in respect of any Contract Year ending more than thirty-six (36) months prior to the date of such notice. If such independent certified public accountant's report shows any overpayment or underpayment by a Party, the other Party shall remit to such Party within thirty (30) days after such Party's receipt of such report, (i) the amount of such overpayment or underpayment, as the case may be, (ii) interest on such overpayment or underpayment, as the case may be, at the prime rate quoted by Chase Manhattan Bank N.A. from the date payment was first due until the date of payment of such overpayment or underpayment, as the case may be, and (iii) if such overpayment or underpayment, as the case may be, exceeds five percent (5%) of the total amount owed for the period then being audited, the reasonable fees and expenses of any independent accountant performing the audit on behalf of such Party.

ARTICLE VII REPRESENTATIONS AND WARRANTIES

7.1 Representation and Warranties of Each Party. Each of WCH and IMPAX hereby represents and warrants to the other Party hereto as follows:

7.1.1 it is a corporation or entity duly organized and validly existing under the laws of the state or other jurisdiction of incorporation or formation;

7.1.2 the execution, delivery and performance of this Agreement by such Party has been duly authorized by all requisite corporate action and do not require any shareholder action or approval;

7.1.3 it has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder;

7.1.4 the execution, delivery and performance by such Party of this Agreement and its compliance with the terms and provisions hereof does not and will not conflict with or result in a breach of any of the terms and provisions of or constitute a default under (i) any other contract entered into by such Party; (ii) a loan agreement, guaranty, financing agreement, agreement affecting a product or other agreement or instrument binding or affecting it or its property; (iii) the provisions of its charter or operative documents or by laws; or (iv) any order, writ, injunction or decree of any court or governmental authority entered against it or by which any of its property is bound; and

7.1.5 is in compliance with all applicable laws and regulations relating to its activities under this Agreement.

7.2 Representations and Warranties of IMPAX.

7.2.1 IMPAX hereby represents and warrants to WCH with respect to each delivery of Products that:

(i) the Products (a) have been Manufactured in the United States; (b) have been Manufactured, stored and shipped in accordance with GMPs and all applicable laws, rules, regulations or requirements in effect at the time of Manufacture; (c) conform to the Specifications, are free from defects and are merchantable; (d) at the point of shipment to WCH or WCH's designee are not adulterated or misbranded; and (e) have been shipped and stored in accordance with approved procedures agreed between WCH and IMPAX;

(ii) the D-12 Products and D-24 Products are pharmaceutically equivalent and bioequivalent to CLARITIN-D(R) 12-hour Extended Release Tablets and CLARITIN-D(R) 24-hour Extended Release Tablets, respectively;

(iii) IMPAX has good and marketable title to all Products and Products are free from all liens, charges, encumbrances and security interests;

(iv) to the knowledge of IMPAX, (A) as of the Effective Date and (B) thereafter, except as disclosed in writing by IMPAX to WCH, the Manufacture, use, importation, offer for sale and sale of Products do not infringe any intellectual property rights of any Third Party, including but not limited to U.S. Patents 4,659,716; 4,863,931; ++; and 5,314,697 and any foreign counterparts thereof;

(v) the Facilities conform in all respects to applicable law governing such Facilities; and

(vi) neither IMPAX nor its Affiliates used in any capacity the services of any person debarred under the U.S. Generic Drug Enforcement Act, 21 USA ss.335a(k)(l) and further it did not use any person who has been convicted of a crime as defined under the Generic Drug Enforcement Act in connection with the Manufacture of Products or any service rendered to WCH.

7.2.2 IMPAX hereby represents and warrants with respect to the IMPAX Patents and Technical Information:

(i) IMPAX has no knowledge that the IMPAX Patents (a) are not valid and enforceable; or (b) are dominated or the practice of then claimed subject matter infringes the intellectual property rights of any Third Party in the Territory as of the Effective Date;

(ii) IMPAX has the full right, power and authority to grant the licenses set forth in Sections 2.1 and 2.2;

(iii) IMPAX has not previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in the Products, the IMPAX Patents or the Technical Information in the OTC Field in the Exclusive Territory; and

(iv) IMPAX is the sole and exclusive owner of the IMPAX Patents and Technical Information free and clear of all liens, charges, encumbrances and security interests.

++ Confidential portions omitted and filed separately with the Commission.

7.3 Representations and Warranties of WCH.

7.3.1 WCH hereby represents and warrants to IMPAX that with respect to any Product that WCH or one of its Affiliates Manufactures pursuant to Section 2.2:

- (i) such Products (a) have been Manufactured, stored and shipped in accordance with GMPs and all applicable laws, rules, regulations or requirements in effect at the time of Manufacture; (b) conform to the Specifications, are free from defects and are merchantable; (c) are not adulterated or misbranded; and (d) have been shipped and stored in accordance with approved procedures agreed between WCH and IMPAX;
- (ii) WCH's and/or its Affiliates' manufacturing facilities for such Products conform in all respects to applicable law governing such facilities; and
- (iii) neither WCH nor its Affiliates used in any capacity the services of any person debarred under the U.S. Generic Drug Enforcement Act, 21 USA ss.335a(k)(l) and further it did not use any person who has been convicted of a crime as defined under the Generic Drug Enforcement Act in connection with the Manufacture of Products.

7.3.2 WCH hereby represents and warrants to IMPAX that all Products which WCH shall market, store, sell, distribute, import and export under this Agreement shall have been marketed, stored, sold, distributed, imported and exported in accordance with applicable law.

7.4 Representation by Legal Counsel. Each Party hereto represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption shall exist or be implied against the Party which drafted such terms and provisions.

7.5 No Further Warranties. EXCEPT AS OTHERWISE SPECIFICALLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, CONCERNING THE PRODUCTS OR THE MERCHANTABILITY OR FITNESS THEREOF FOR ANY PURPOSE.

ARTICLE VIII INDEMNIFICATION AND INSURANCE

8.1 Indemnification.

8.1.1 IMPAX shall indemnify, defend and hold harmless WCH, its Affiliates and their respective directors, officers, employees and agents from and against all damages, losses, liabilities, expenses, claims, demands, suits,

penalties or judgments or administrative or judicial orders (including reasonable attorneys' fees and expenses) ("Costs") incurred, assessed or sustained by or against WCH, its directors, officers, employees or agents with respect to or arising out of (i) the negligent or willful acts or omissions or strict liability of IMPAX; (ii) any breach by IMPAX of its representations, warranties or covenants hereunder; (iii) any Recall or Seizure attributable to IMPAX's performance; (iv) any allegation that the Manufacture, importation, sale, offer for sale or use of any Product in the United States infringes any Patent or other proprietary or protected right, other than trademark rights; or (v) IMPAX's failure to comply with any applicable law, regulation or order (including but not limited to environmental laws, regulations and orders, and laws and orders relating to the Manufacture, storage, sale, import and export of Products).

8.1.2 WCH shall indemnify, defend and hold harmless IMPAX, its Affiliates and their respective directors, officers, employees and agents from and against all damages, losses, liabilities, expenses, claims, demands, suits, penalties or judgments or administrative or judicial orders (including reasonable attorneys' fees and expenses) incurred, assessed or sustained by or against IMPAX, its directors, officers, employees or agents with respect to or arising out of (i) the negligent or willful acts or omissions or strict liability of WCH; or (ii) any breach by WCH of its representations, warranties or covenants hereunder; or (iii) any Recall or Seizure attributable to WCH's performance; (iv) any allegation that the importation, sale, offer for sale or use of any Product by WCH in any country in the Exclusive Territory outside the United States infringes any Patent or other proprietary or protected right; or (v) WCH's failure to comply with any applicable law, regulation or order (including but not limited to environmental laws, regulations and orders, and laws and orders related to the Manufacture (if WCH is Manufacturing Product pursuant to Section 2.2), storage, marketing, distribution, sale, import and export of the Products).

8.1.3 Each Party and its Affiliates and their respective directors, officers, employees or agents (an "Indemnified Party") shall promptly notify the other Party (the "Indemnifying Party"), in writing, of any claim asserted or threatened against such Indemnified Party for which such Indemnified Party is entitled to indemnification hereunder from the Indemnifying Party. With respect to any such claim the Indemnified Party shall, at no out-of-pocket expense to it, reasonably cooperate with and provide such reasonable assistance to such Indemnifying Party as such Indemnifying Party may reasonably request. Such reasonable assistance may include, without limitation, providing copies of all relevant correspondence and other materials that the Indemnifying Party may reasonably request. The obligations of an Indemnifying Party under Sections 8.1.1 and 8.1.2 are conditioned upon the delivery of written notice to the Indemnifying Party of any asserted or threatened claim promptly after the Indemnified Party becomes aware of such claim; provided, that the failure of the Indemnified Party to give such notice or any delay thereof shall not affect the Indemnified Party's right to indemnification hereunder, except to the extent that such failure or delay impairs the Indemnifying Party's ability to defend or contest any such claim. The Indemnifying Party shall have the right to assume the defense of any suit or claim for which indemnification is sought. If the Indemnifying Party defends the suit or claim, the Indemnified Party may participate in (but not control) the defense thereof at its sole cost and expense. An Indemnifying Party may not settle a suit or claim, without the consent of the Indemnified Party, if such settlement would impose any monetary

obligation on the Indemnified Party for which indemnification is not provided hereunder or require the Indemnified Party to submit to an injunction or otherwise limit the Indemnified Party's rights under this Agreement. Any payment made by an Indemnifying Party to settle any such suit or claim shall be at its own cost and expense.

8.1.4 With respect to any claim by one Party against the other Party arising out of the performance or failure of performance of the other Party under this Agreement, the Parties expressly agree that the liability of such Party to the other Party for such breach shall be limited under this Agreement or otherwise at law or equity to direct damages only and in no event shall a Party be liable for lost profits, punitive, exemplary or consequential damages; provided, however, that such limitation shall not apply with respect to the obligations of either Party to indemnify the other under Sections 8.1.1 or 8.1.2 hereof in connection with a liability to a Third Party.

8.2 Insurance. Each Party shall maintain the following kinds of insurance with the minimum limits set forth below.

Kind of Insurance	Minimum Limits
-----	-----
Commercial General Liability, including Contractual, Completed Operations and Products Liability	\$2,000,000 Per Occurrence \$5,000,000 Aggregate
Workers Compensation	Statutory with Employer's Liability of not less than \$1,000,000 Per Accident/Disease
Automobile Bodily Injury Liability (including hired automobile and non-ownership Liability)	\$1,000,000 Each Accident Combined Single Limit

WCH may be self insured for such amounts. Upon request, IMPAX shall furnish insurance certificates as directed by WCH, satisfactory in form and substance to WCH, showing the above coverages, and providing for at least ten (10) days' prior written notice to WCH by the insurance company of cancellation or modification. WCH shall be named as an additional insured on the IMPAX's policies. Coverage shall be procured with carriers having an A.M. Best rating of A-VII or better.

**ARTICLE IX
TERM AND TERMINATION**

9.1 Term. This Agreement shall commence on the Effective Date and continue, unless sooner terminated as set forth below in this Article IX or in Article XII or Sections 5.3.2, 6.3.2 or 14.10, until the later to occur of (i) the fifth anniversary of the Launch date of a Product in the United States or
(ii) the date of the expiration of the last to expire of the IMPAX Patents (the "Term").

9.2 Termination by Either Party.

9.2.1 If either Party shall materially breach any of its obligations hereunder and shall fail to correct such breach within thirty (30) days after the other Party shall have given notice to it thereof, the aggrieved Party shall be entitled to notify the other Party that it intends to terminate this Agreement unless such breach is corrected and may so terminate ten (10) days after the end of such thirty (30) day period if such breach is continuing, unless, to the extent the breach can be cured, the time period of thirty (30) days is not sufficient to cure such breach in which event the Party in breach shall have such additional time as shall be reasonably necessary to cure such breach, but in no event to exceed six (6) months. Such termination shall not give rise to the payment of any penalty, damages or indemnity by the terminating Party.

9.2.2 If either Party by voluntary or involuntary action goes into liquidation, dissolves or files a petition for bankruptcy or suspension of payments, is adjudicated bankrupt, has a receiver or trustee appointed for its property or estate, becomes insolvent or makes an assignment for the benefit of creditors, the other Party shall be entitled by notice in writing to such Party to terminate this Agreement forthwith. Such termination shall not give rise to the payment of any penalty, damages or indemnity by the terminating Party.

9.2.3 If, upon the decision of a court of competent jurisdiction from which either no appeal can be taken or the time for an appeal has expired without an appeal having been filed, a claim is upheld that the Manufacture, storage, importation, sale, offer to sell or use of the Product, or Products, respectively, infringes any Patent or other proprietary or protected right (other than trademark rights) of a Third Party, then either Party shall have the right to immediately terminate this Agreement, upon written notice to the other Party, as to the country or other geographic area, and Product, or Products, respectively, covered by the Patent or other proprietary or protected right. Upon any such termination by WCH, WCH shall have no further rights to such Product or Products in that country or geographic area.

9.3 Termination by WCH.

9.3.1 WCH may terminate this Agreement upon ten (10) days' written notice to IMPAX either in its entirety, or with respect to the Product to which the event relates, if any of the following events does not occur by the date set forth opposite such event:

Event ----	Date -----
(i) Successful completion of scale-up and validation (based on WCH's approval of final validation report) for the D-12 Product	The later of (i) November 30, 2002 or (ii) ninety (90) days from the date on which WCH provides IMPAX with the ++ for the D-12 Product or notifies IMPAX in writing that none are required
(ii) Successful completion of scale-up and validation (based on WCH's approval of final validation report) for the D-24 Product	The later of (i) June 30, 2003 or (ii) ninety (90) days from the date on which WCH provides IMPAX with the ++ for the D-24 Product or notifies IMPAX in writing that none are required
(iii) Final ANDA approval (which includes without limitation WCH's consumer labeling and blister packaging) of D-12 Product by FDA	August 30, 2003
(iv) Final ANDA approval (which includes without limitation WCH's consumer labeling and blister packaging) of D-24 Product by FDA	March 31, 2004
(v) Failure to deliver at least seventy-five percent (75%) of the Launch quantities of D-12 Product consistent with the forecasts required by Section 4.2	Four and one-half (4 1/2) months after the later of (i) receipt of WCH's purchase order therefor or (ii) the date on which WCH provides IMPAX with the ++ for the D-12 Product or notifies IMPAX in writing that none are required

++ Confidential portions omitted and filed separately with the Commission.

Event -----	Date -----
(vi) Failure to deliver at least seventy-five percent (75%) of the Launch quantities of D-24 Product consistent with the forecasts required by Section 4.2	Four and one-half (4 1/2) months after the later of (i) receipt of WCH's purchase order therefor or (ii) the date on which WCH provides IMPAX with the ++ for the D-24 Product or notifies IMPAX in writing that none are required

Such termination shall not give rise to the payment of any penalty, damages or indemnity by either Party and WCH shall have no further rights under Sections 2.1 and 2.2, except where the event is a failure to deliver Launch quantities of the D-12 and D-24 Product in which case the provisions of Section 9.5.1 shall apply.

9.3.2 WCH may terminate this Agreement either in its entirety or with respect to any Product upon three (3) months' written notice to IMPAX. If WCH terminates this Agreement pursuant to this Section 9.3.2, then WCH shall make the following payments with respect to the Product so terminated:

Event -----	Payment -----
I. D-12 Product	
If on or before the date on which notice of termination is given for the D-12 Product the event described in Section 6.1(viii) has not occurred	\$++
or	
If on or before the date on which notice of termination is given for the D-12 Product the event described in Section 6.1(viii) has occurred but the event described in Section 6.1(x) has not occurred	\$++
or	
If on or before the date on which notice of termination is given for the D-12 Product the event described in Section 6.1(x) has occurred	\$++

++ Confidential portions omitted and filed separately with the Commission.

II. D-24 Product

If on or before the date on which notice of termination is given for the D-24 Product the event described in Section 6.1(ix) has not occurred	\$++
or	
If on or before the date on which notice of termination is given for the D-24 Product the event described in Section 6.1(ix) has occurred but the event described in Section 6.1(xi) has not occurred	\$++
or	
If on or before the date on which notice of termination is given for the D-24 Product the event described in Section 6.1(xi) has occurred	\$++

It is understood and agreed that the amounts set forth above are in lieu of and not in addition to the license payments for the corresponding event set forth in

Section 6.1 and that, effective upon termination, WCH's obligation to make future license payments with respect to any terminated Product shall be canceled. Except as specifically set forth above, such termination shall not give rise to the payment of any penalty, damages or indemnification by either Party and WCH shall have no further rights to the Product or Products to which such termination applies.

9.3.3 In addition to, and not in limitation on, WCH's rights under Section 9.2.3, WCH may terminate this Agreement in its entirety or with respect to any Product immediately (i) if FDA takes any action (provided that with respect to such action either (a) no appeal can be taken or the time for an appeal has expired without an appeal having been filed or an appeal has been filed and FDA's action has been upheld or (b) such action is a final regulatory action), the result of which is to prohibit the Manufacture, storage, importation, sale, offer for sale or use of the Products or a Product, respectively; (ii) if the Loratadine to be used by IMPAX to Manufacture Product does not meet the ++ upon completion of the initial analysis by ++ (or such other contract laboratory specified by WCH); provided that such notice of termination is given by WCH in this subparagraph (ii) by no later than March 31, 2003; (iii) if the Loratadine to be used by IMPAX to Manufacture Product is not determined upon testing by WCH to be outside the scope of ++ or any Patent that issues based thereon; or (iv) if a decision is rendered in favor of Schering in any of the Patent Litigations either by a United States District Court and the time for an appeal has expired without an appeal having been filed, or by the United States Court of Appeals for the Federal Circuit and the time for an appeal has expired without an appeal having been filed, or by the United States Supreme Court. Notwithstanding the foregoing, (a) if a United States District Court renders a decision in favor of Schering with respect to the '716 Patent, then WCH's obligation to make any further payments under Section 6.1 shall be suspended until such time as the decision in favor of

++ Confidential portions omitted and filed separately with the Commission.

Schering is reversed and a final decision from which no appeal can be taken is entered in IMPAX's favor in such case; and (b) if a United States District Court renders a decision in favor of Schering with respect to the '697 Patent, then WCH's obligation to make any further payments under Section 6.1 with respect to the D-24 Product shall be suspended until such time as the decision in favor of Schering is reversed and a final decision from which no appeal can be taken is entered in IMPAX's favor in such case. Such termination shall not give rise to the payment of any penalty, damages or indemnity by WCH and WCH shall have no further rights to such Product so terminated.

9.3.4 In addition to, and not in limitation on, WCH's rights under Section 9.2.3, WCH may terminate this Agreement with respect to any Product in a country (other than the United States which is provided for in Section 9.3.3) in which a Regulatory Authority has taken any action (with respect to such action either (a) no appeal can be taken, or the time for an appeal has expired without an appeal having been filed or an appeal has been filed and such Regulatory Authorities' action has been upheld or (b) such action is a final regulatory action), the result of which is to prohibit the Manufacture, storage, importation, sale, offer for sale or use of the Products or a Product respectively, or an action is commenced alleging that the Manufacture, storage, importation, sale, offer for sale or use of the Products or a Product, respectively, infringe any Patent or other proprietary or protected right of any Third Party in such country. Such termination shall not give rise to the payment of any penalty, damages or indemnity by WCH and WCH shall have no further rights to such country so terminated.

9.4 Termination by IMPAX.

9.4.1 If IMPAX requests in writing that WCH file an application for Regulatory Approval for a Product in the OTC Field in a particular country in the Exclusive or Semi-Exclusive Territory (other than the United States) and if WCH does not commence using Commercially Reasonable Efforts to submit such an application within six (6) months, then IMPAX, at its option and as its sole and exclusive remedy, may terminate this Agreement with respect to such Product in such country (thereby modifying the Exclusive or Semi-Exclusive Territory to exclude such Product in such country) by providing six (6) months' written notice to WCH, and WCH shall have no further rights to such Product in such country. Such modification shall not give rise to the payment of any penalty, damages or indemnification by either Party.

9.4.2 If WCH fails to use Commercially Reasonable Efforts to Launch a Product in a country of the Exclusive or Semi-Exclusive Territory within one (1) year after having obtained FTO Status for such Product in the OTC Field in such country, IMPAX, at its option and as its sole and exclusive remedy, may terminate this Agreement with respect to such Product in such country (thereby modifying the Exclusive or Semi-Exclusive Territory to exclude such Product in such country) by providing six (6) months' written notice to WCH. Such modification shall not give rise to the payment of any penalty, damages or indemnification by either Party and WCH shall have no further rights to such Product in such country.

9.5 Effect of Expiration or Termination.

9.5.1 Upon expiration of this Agreement pursuant to Section

9.1 (i) or (ii) or termination by WCH pursuant to Section 9.2.2, 9.3.1(v) or 9.3.1(vi) or termination by IMPAX pursuant to 9.2.3 (provided that in the case of termination by IMPAX pursuant to Section 9.2.3 only, (i) upon IMPAX's written request prior to termination by IMPAX, WCH shall cooperate with IMPAX in attempting to identify a means to address or avoid the subject infringement, (ii) the license set forth below is limited to the countries or geographic area to which such termination applies and (iii) WCH provides IMPAX with an indemnity agreement acceptable to IMPAX for any damages assessed against IMPAX, arising out of WCH's exercise of the license set forth below, for infringement of such Patent or other proprietary or protected right, such acceptance not to be unreasonably withheld or delayed), WCH shall have the fully paid-up, royalty free, perpetual, irrevocable (except that such license may be terminated pursuant to the proviso set forth below), non-exclusive license, with the right to grant sublicenses, to make, have made, market, promote, use, distribute, sell, have sold, import and export Products for the OTC Field within the Territory pursuant to the Regulatory Documents, the IMPAX Patents and IMPAX's Technical Information (including manufacturing know-how); provided that if WCH breaches the terms of the license set forth in this Section 9.5.1 and fails to correct such breach within ten (10) days after notice in writing from IMPAX, IMPAX may terminate this license if such breach is continuing by notice in writing given at the end of such ten (10) day period.

9.5.2 Upon termination of this Agreement by WCH for an uncured material breach of this Agreement pursuant to Section 9.2.1, WCH shall have a fully paid up, royalty free, perpetual, irrevocable (except that such license may be terminated pursuant to the proviso set forth below), non-exclusive license, with the right to grant sublicenses, to make, have made, market, promote, use, distribute, sell, have sold, import and export Products for the OTC Field within the Territory pursuant to the Regulatory Documents, the IMPAX Patents and IMPAX's Technical Information (including manufacturing know-how); provided that if WCH breaches the terms of the license set forth in this Section 9.5.2 and fails to correct such breach within ten (10) days after notice in writing from IMPAX, IMPAX may terminate this license if such breach is continuing by notice in writing given at the end of such ten (10) day period.

9.5.3 In the event that WCH terminates this Agreement under the circumstances described in Section 9.5.1 or 9.5.2, (i) IMPAX shall promptly but no later than within thirty (30) days after receipt of notice of such termination, furnish to WCH, on a non-exclusive basis, all of IMPAX's Technical Information (including manufacturing know-how) as relates to Product for the OTC Field in the Territory and (ii) IMPAX shall, within thirty (30) days of a request by WCH, furnish to WCH and/or its Affiliates all Regulatory Documents which relate to Product for the OTC Field in the Territory. Upon WCH's request, IMPAX shall within the same period deliver to WCH or its designees full copies, at WCH's expense, (both paper and electronic, where available) of any Regulatory Documents in IMPAX's or its Affiliates' possession or control and provide all technical assistance, at WCH's cost, reasonably requested by WCH. IMPAX agrees to promptly execute and deliver any additional documents and instruments, and perform any additional acts, that may be reasonably necessary to effect this right.

9.5.4 Except as otherwise set forth in this Agreement, neither Party shall be entitled to any compensation whatsoever as a result of expiration or termination of this Agreement, but without limiting either Party's damages for any breach of this Agreement.

9.5.5 Termination or expiration of this Agreement, in whole or in part, shall be without prejudice to the right of either Party to receive all payments accrued and unpaid at the effective date of such termination or expiration, without prejudice to the remedy of either Party in respect to any previous breach of any of the representations, warranties or covenants herein contained and without prejudice to any other provisions hereof which expressly or necessarily call for performance after such termination or expiration.

9.5.6 The following provisions shall survive the expiration or termination of this Agreement: Section 9.5 and Articles I, VII, VIII, X and XIV, in each case for the time periods and subject to the limitations set forth therein.

ARTICLE X CONFIDENTIALITY

10.1 Nondisclosure Obligation. Each of IMPAX and WCH shall use only in connection with the Manufacture of Product or otherwise in accordance with this Agreement and shall not disclose to any Third Party the Confidential Information received by it from the other Party pursuant to this Agreement, without the prior written consent of the other Party. The foregoing obligations shall survive for a period of five (5) years after the termination or expiration of this Agreement. These obligations shall not apply to Confidential Information that:

- (i) is known by the receiving Party at the time of its receipt, and not through a prior disclosure by the disclosing Party, as documented by business records;
- (ii) is at the time of disclosure or thereafter becomes published or otherwise part of the public domain without breach of this Agreement by the receiving Party;
- (iii) is subsequently disclosed to the receiving Party by a Third Party who has the right to make such disclosure;
- (iv) is developed by the receiving Party independently of the Confidential Information received from the disclosing Party and such independent development can be documented by the receiving Party; or
- (v) is required by law, regulation, rule, act or order of any governmental authority or agency to be disclosed by a Party, provided that notice is promptly delivered to the other Party in order to provide an opportunity to seek a protective order or other similar order with respect to such Confidential Information and thereafter the disclosing Party

discloses to the requesting entity only the minimum Confidential Information required to be disclosed in order to comply with the request, whether or not a protective order or other similar order is obtained by the other Party.

10.2 Permitted Disclosures. Each Party may disclose the other Party's Confidential Information to its employees and Affiliates on a need-to-know basis and to its agents, counsel or consultants to the extent required to accomplish the purposes of this Agreement; provided that the recipient Party obtains prior agreement from such agents and consultants to whom disclosure is to be made to hold in confidence and not make use of such Confidential Information for any purpose other than those permitted by this Agreement. WCH may disclose IMPAX Confidential Information in connection with seeking Regulatory Approval of Products. Each Party will use at least the same standard of care as it uses to protect proprietary or confidential information of its own to ensure that such employees, agents, consultants, and Affiliates do not disclose or make any unauthorized use of the other Party's Confidential Information, but in no event less than a reasonable degree of care.

10.3 Disclosure of Agreement. Neither IMPAX nor WCH shall release to any Third Party or publish in any way any non-public information with respect to the terms of this Agreement without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed, provided that, either Party may disclose the terms of this Agreement

(i) to the extent required to comply with applicable laws, including, without limitation the rules and regulations promulgated by the United States Securities and Exchange Commission; provided, further, that prior to making any such disclosure, the Party intending to so disclose the terms of this Agreement shall (a) provide the nondisclosing Party with written notice of the proposed disclosure and an opportunity to review and comment on the intended disclosure which is reasonable under the circumstances and (b) shall seek confidential treatment for as much of the disclosure as is reasonable under the circumstances, including, without limitation, seeking confidential treatment of any information as may be requested by the other Party; or

(ii) to one or more Third Parties and/or their advisors in connection with a proposed spin-off, joint venture, divestiture, merger or other similar transaction involving all, or substantially all, of the assets or business of the disclosing Party to which this Agreement relates or to lenders, investment bankers and other financial institutions of its choice solely for purposes of financing the business operations of such Party; provided, further, that either (a) upon the written consent of the other Party or (b) if the disclosing Party uses reasonable efforts to obtain a signed confidentiality agreement with such Third Parties with respect to such information on terms no less restrictive than those contained in this Article X.

10.4 Publicity. Subject to Section 10.3, all publicity, press releases and other announcements relating to this Agreement or the transactions contemplated hereby shall be reviewed in advance by, and shall be subject to the approval of, both Parties.

ARTICLE XI

TRADEMARKS; INFRINGEMENT OF IMPAX PATENTS

11.1 Trademarks. WCH may advertise, promote, market and sell Products under any trademarks, copyrights, tradenames or logos, whether registered or unregistered, selected by WCH in its sole discretion. IMPAX shall have no right, title or interest in or to any such trademark, copyright, tradename or logo. So long as WCH or any Affiliate of WCH shall have any interest in any such trademark, copyright, tradename, or logo, whether registered or unregistered, whether as proprietor, owner, or licensee in any country of the world, IMPAX shall not adopt, use, apply for registration, register or own such trademark, copyright, tradename, or logo, or any such item confusingly similar thereto in any country of the world, or take any action which, in WCH's sole opinion, weakens or undermines WCH's proprietary rights.

11.2 Infringement of IMPAX Patents.

11.2.1 Each Party shall promptly report in writing to the other Party during the term of this Agreement any known infringement or suspected infringement of any of the IMPAX Patents in the Territory by manufacture, use or sale of a Product on a commercial scale in derogation of the rights granted to WCH hereunder (hereinafter, a "Related Infringement") of which it becomes aware, and shall provide the other Party with all available evidence supporting said infringement or suspected infringement.

11.2.2 Except as provided in Section 11.2.4, IMPAX shall have the right to initiate an infringement or other appropriate suit anywhere in the Territory against any Third Party who at any time has infringed, or is suspected of infringing, any of the IMPAX Patents. IMPAX shall give WCH sufficient advance notice of its intent to file any suit on account of a Related Infringement and the reasons therefor, and shall provide WCH with an opportunity to make suggestions and comments regarding such suit. IMPAX shall keep WCH promptly informed, and shall from time to time consult with WCH regarding the status of any such suit on account of a Related Infringement and shall provide WCH with copies of all documents filed in, and all written communications relating to, such suit.

11.2.3 IMPAX shall have the sole and exclusive right to select counsel for any suit referred to in Section 11.2.2 and shall, except as provided below, pay all expenses of the suit, including without limitation attorneys' fees and court costs. In the event that WCH elects not to contribute to the costs of such litigation, IMPAX shall be entitled to retain any damages, royalties, settlement fees or other consideration for infringement resulting therefrom. If necessary, WCH shall join as a Party to the suit but shall be under no obligation to participate except to the extent that such participation is required as the result of being a named Party to the suit. WCH shall offer reasonable assistance to IMPAX therewith at no charge to IMPAX except for

reimbursement of reasonable out-of-pocket expenses incurred in rendering such assistance. WCH shall have the right to participate and be represented in any such suit by its own counsel at its own expense. IMPAX shall not settle any such suit on terms which grant any license to any other Party in derogation of the rights granted to WCH hereunder without obtaining the prior written consent of WCH, which consent shall not be unreasonably withheld.

11.2.4 In the event that IMPAX elects not to initiate an infringement or other appropriate suit pursuant to Section 11.2.2 above on account of a Related Infringement after reasonable efforts to abate such Related Infringement without litigation have failed, but in no event later than one hundred and twenty (120) days after WCH's notice to IMPAX under Section 11.2.1, IMPAX shall promptly advise WCH of its intent not to initiate such a suit, WCH shall have the right, at the expense of WCH, of initiating an infringement or other appropriate suit against the Party or Parties committing such Related Infringement. In exercising its rights pursuant to this Section 11.2.4, WCH have the sole and exclusive right to select counsel and shall, except as provided below, pay all expenses of the suit including without limitation attorneys' fees and court costs. IMPAX, in its sole discretion, may elect within sixty (60) days after the commencement of such litigation, to contribute to the costs incurred by WCH in connection with such litigation, and, if it so elects, any damages, royalties, settlement fees or other consideration received by WCH as a result of such litigation shall be shared by WCH and IMPAX pro rata based on their respective sharing of the costs of such litigation provided that such pro rata share shall not exceed fifty percent (50%) unless WCH has consented to a higher share in writing. In the event that IMPAX elects not to contribute to the costs of such litigation, WCH shall be entitled to retain any damages, royalties, settlement fees or other consideration for infringement resulting therefrom. If necessary, IMPAX shall join as a Party to the suit but shall be under no obligation to participate except to the extent that such participation is required as a result of being named a Party to the suit. At WCH's request, IMPAX shall offer reasonable assistance to WCH in connection therewith at no charge to WCH except for reimbursement of reasonable out-of-pocket expenses incurred in rendering such assistance. IMPAX shall have the right to participate and be represented in any such suit by its own counsel at its own expense.

ARTICLE XII FORCE MAJEURE

12.1 Force Majeure. If the production, delivery, acceptance, or use of Products specified for delivery under this Agreement, or the performance of any other obligation of one of the Parties hereunder is prevented, restricted or interfered with by reason of any cause or event beyond the reasonable control of such Party and without the fault or negligence of such Party, the Party so affected, upon prompt notice to the other Party (including a statement of impact), shall be excused from performing such obligation during the continuance of such event. If such event continues for a period of ninety (90) consecutive days or more the other Party may terminate this Agreement by notice in writing provided that such event of force majeure is continuing. If as a result or any of the force majeure events described above, IMPAX is unable to fully supply WCH's orders hereunder, IMPAX shall allocate all available quantities of Materials and Products to WCH in the ratio that the quantities ordered by WCH in twelve (12) month period immediately preceding such force majeure event bears to IMPAX's requirements for it own use and for supply to Third Parties for that same period; provided that if this Agreement has not been in effect for a full twelve (12) month period, then such shorter period shall be used in lieu of a twelve (12) month period.

ARTICLE XIII
NOTICES

13.1 Ordinary Notices. Correspondence, reports, documentation, and any other communication in writing between the Parties in the course of ordinary implementation of this Agreement shall be delivered by hand, sent by facsimile or overnight courier to the employee or representative of the other Party who is designated by such other Party to receive such written communication at the address or facsimile numbers specified by such employee or representative.

13.2 Extraordinary Notices. Extraordinary notices and communications (including without limitation, notices of termination, force majeure, material breach, change of address, requests for disclosure of Confidential Information, claims or indemnification) shall be in writing and sent to each Party by prepaid registered or certified airmail, or by facsimile confirmed by prepaid registered or certified airmail letter (and shall be deemed to have been properly served to the addressee upon receipt of such written communication) to the address set forth in Section 13.3 or such other address as notified in writing by such Party to the other Party.

13.3 Addresses.

If to WCH:

Wyeth Consumer Healthcare

Five Giralda Farms
Madison, New Jersey 07940
Attention: President
Facsimile No.: 973-660-7199

With a copy to:

Wyeth
Five Giralda Farms
Madison, New Jersey 07940
Attention: General Counsel Facsimile No.: 973-660-7050

If to IMPAX:

Impax Laboratories, Inc.
3735 Castor Avenue
Philadelphia, Pennsylvania 19124

Attention: Barry R. Edwards, Co-Chief Executive Officer Facsimile No.: 215-289-5932

With a copy to:

Sol Genauer, Esq.

Blank, Rome, Comisky & McCauley LLP

One Logan Square
Philadelphia, Pennsylvania 19103-6998 Facsimile No.: 215-569-5628

**ARTICLE XIV
MISCELLANEOUS**

14.1 Governing Law. This Agreement shall be construed in accordance with and governed by the law of the State of New York, without giving effect to its conflict of laws provisions.

14.2 Equal Opportunity Clause. The Equal Opportunity Clause required by Executive Orders 11246, as amended (41-CFR 60-1.4) and 11375, the Employment Assistance to Veterans Clause required by Executive Order 11701 (41 CFR 60-250.4), the Vietnam Era Veteran Readjustment Act of 1972, the Employment of the Handicapped Clause required by the Rehabilitation Act of 1973 (41 CFR 60-741.4) and the Americans with Disabilities Act of 1991 are part of this Agreement and binding upon each Party unless exempted by rules, regulations or orders of the Secretary of Labor. IMPAX agrees that the applicable clause with regard to the utilization of minority contractors set forth at 41 CFR 1-1.303 and the applicable clause with regard to the Utilization of Small Business Concerns and Small Business Concerns Owned and Controlled by Socially and Economically Disadvantaged Individuals set forth at 41 CFR 1-1.13 are incorporated herein by reference, as applicable. IMPAX agrees to provide information and documentation with respect to the foregoing to WCH upon request.

14.3 Assignment. This Agreement shall not be assignable or transferable by either Party hereto without the prior written consent of the other Party, except that either Party may assign this Agreement without the other Party's consent to the successor or the transferee of all, or substantially all, of the Products, assets or business to which this Agreement relates or to one of its Affiliates; provided that if IMPAX is the assigning Party, IMPAX also transfers the Facility to such assignee. IMPAX shall not subcontract any of its work hereunder without WCH's prior written consent and any such consent given by WCH shall not release IMPAX from its obligations hereunder. WCH's sublicensing of its obligations under this Agreement shall not release WCH from its obligations hereunder. This Agreement shall be binding upon and shall inure to the benefit of the Parties and their successors and permitted assigns.

14.4 Entire Agreement. This Agreement and all Exhibits attached hereto (as the same may be amended from time to time by the written agreement of the Parties) constitute the entire agreement between the Parties with respect to the subject matter hereof and supersedes all other documents, agreements, verbal consents, arrangements and understandings between the Parties with respect to

the subject matter hereof. This Agreement shall not be amended orally, but only by an agreement in writing, signed by both Parties that states that it is an amendment to this Agreement.

14.5 Severability. If any term of this Agreement shall be found to be invalid, illegal or unenforceable, it is the intention of the parties that the remainder of this Agreement shall not be affected thereby; provided that neither Party's rights under this Agreement are materially adversely affected.

14.6 Independent Contractor. IMPAX shall act as an independent contractor and neither Party shall have any authority to represent or bind the other Party in any way.

14.7 No Waiver. Any waiver by one Party of any right or such Party or obligation of the other Party must be in writing signed by the Party waiving such right or performance of such obligation and shall not operate as a waiver of any subsequent right or obligation.

14.8 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be an original and all of which together shall constitute one and the same Agreement.

14.9 Compliance Issues. The Parties acknowledge that the export of technical data, materials or products is subject to the exporting Party receiving the necessary export licenses and that the Parties cannot be responsible for any delays attributable to export controls which are beyond the reasonable control of either Party and any such delay shall not constitute a force majeure event or constitute a breach of this Agreement. The Parties agree that regardless of any disclosure made by the Party receiving an export of any ultimate destination of any technical data, materials or products, the receiving Party will not re-export either directly or indirectly, any technical data, material or products without first obtaining the applicable validated or general license from the United States Department of Commerce, FDA and/or any other agency or department of the United States Government as required.

14.10 HSR Filing. To the extent necessary, each of IMPAX and WCH shall file as soon as practicable after the date this Agreement was signed by each of the Parties, with the Federal Trade Commission (the "FTC") and the Antitrust Division of the United States Department of Justice (the "Antitrust Division") the notification and report form (the "Report") required under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the rules and regulations promulgated thereunder ("HSR Act") with respect to the transactions as contemplated hereby and shall reasonably cooperate with the other Party to the extent necessary to assist the other Party in the preparation of its Report and to proceed to obtain necessary approvals under the HSR Act, including but not limited to the expiration or earlier termination of any and all applicable waiting periods required by the HSR Act. Each Party shall bear its own expenses, including, without limitation, legal fees, incurred in connection with preparing such filings. If a Report is filed by the Parties under the HSR Act, then the Effective Date shall be the date upon which the necessary approvals have been obtained under the HSR Act or that the notice and waiting period under the HSR Act has expired or been terminated.

If the Parties determine that no Report is required to be filed under the HSR Act, the Effective Date shall be the date first written above.

In the event that a Report is required to be filed under the HSR Act, either Party may, prior to the Effective Date, terminate this Agreement by written notice to the other Party, if, within one hundred twenty (120) days after this Agreement is signed by each of the Parties, approval of the transactions contemplated by this Agreement under the HSR Act has not been obtained or the notice and waiting period, as may be extended by the FTC, under the HSR Act has not expired without adverse action regarding this Agreement or the transactions contemplated hereby. If this Agreement is terminated pursuant to this Section 14.10, then, notwithstanding any provision in this Agreement to the contrary, neither Party shall have any further obligation to the other Party with respect to the subject matter of this Agreement except for the obligations set forth in Article X hereof, which obligations shall survive any termination of this Agreement.

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

WYETH,
acting through its Wyeth Consumer Healthcare Division

By: /s/ Gregory Bobbyock

Name: Gregory Bobbyock
Title: Vice President of Global Business
 Development

IMPAX LABORATORIES, INC.

By: /s/ Barry R. Edwards

Name: Barry R. Edwards
Title: Co-Chief Executive Officer

LICENSING, CONTRACT MANUFACTURING & SUPPLY AGREEMENT

between

SCHERING CORPORATION

and

IMPAX LABORATORIES, INC.

LICENSING, CONTRACT MANUFACTURING & SUPPLY AGREEMENT

THIS AGREEMENT, effective as of the last date of signature appearing below (the "Effective Date"), is entered into by and between Schering Corporation, a corporation organized under the laws of New Jersey, with its principal office at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033 (hereafter called "Schering"), and Impax Laboratories, Inc., a corporation organized under the laws of Delaware, with its principal offices at 30831 Huntwood Avenue, Hayward, California 94550 (hereafter called "Impax").

PURPOSE

WHEREAS, Impax desires to manufacture and supply to Schering, and Schering desires to purchase from Impax, Schering's orders of the Product for sale in the Territory (as hereinafter defined).

NOW THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained and intending to be legally bound hereby, the parties hereby agree as follows:

ARTICLE I

DEFINITIONS

In this Agreement, and in the exhibits to this Agreement the following terms, whether used in the singular or plural, shall have the respective meanings set forth below:

1.1. The term "Active Pharmaceutical Ingredient" shall mean loratadine and/or pseudoephedrine sulfate in bulk form conforming to the Active Pharmaceutical Ingredient Specifications.

1.2. The term "Active Pharmaceutical Ingredient Specifications" shall mean the specifications and quality control testing procedures for the Active Pharmaceutical Ingredient set forth in Exhibit 1.2 hereto which conforms to the ANDA for the Product, as amended from time to time by the mutual agreement of the parties hereto.

1.3. The term "Affiliate" shall mean any individual or entity directly or indirectly controlling, controlled by or under common control with, a party to this Agreement. For purposes of this Agreement, the direct or indirect ownership of over fifty percent (50%) of the outstanding voting securities of an entity, or the right to receive over fifty percent (50%) of the profits or earnings of an entity shall be deemed to constitute control. Such other relationship as in fact results in actual control over the management, business and affairs of an entity shall also be deemed to constitute control.

1.4. The term "Agreement" shall mean this agreement and any and all exhibits, appendices and other addenda attached hereto, including as they may be modified from time to time in accordance with the provisions of this Agreement.

1.5. The term "Approved Facilities" shall mean that facilities of Impax located at Buildings No. 1 and No. 2, 30831 Huntwood Avenue, Haywood, California 94545 and its facility located at 3735 Castor Avenue, Philadelphia, PA 19124 and referenced in the Health Registrations as an approved site for the Manufacture of the Product, including without limitation all of the equipment, machinery and facilities of Impax at such location that are used in the Manufacturing, testing, stability oversight, and storage of Product.

1.6. The term "ANDA" shall mean an abbreviated new drug application filed with the FDA seeking approval to market and sell a generic prescription or OTC pharmaceutical product in the Territory and any supplements and amendments, and any such approvals granted by the FDA based upon such application.

1.7. The term "CMC" shall mean the chemistry, manufacturing, and controls section(s) and data in the Health Registrations that cover the chemical composition of the Product and its components and the control and Manufacturing process for the Product, as amended or supplemented from time to time.

1.8. "Commercially Reasonable Efforts" means efforts and resources normally used by a party for a compound or product owned by it or to which it has rights, which is of similar market potential at a similar stage in its product life, taking into account the competitiveness of the marketplace, the proprietary position of the compound or product, the regulatory structure involved, the profitability of the applicable products, and other relevant factors. It is anticipated that the level of efforts and resources may change at different times during the product life cycle of a compound or product.

1.9. The term "Cure Price" shall mean the out-of-pocket cost to Schering for the Product Manufactured by Schering, an Affiliate of its or a Third Party, due to a Supply Failure, failure in Product quality or other failure to comply with the Product Specifications, which Cure Price shall not exceed 125% of the Price set forth on Exhibit 1.29.

1.10. The term "FCA" shall mean Free Carrier as that term is used in Incoterms 2000 and as further set forth in Section 5.2 hereof.

1.11. The term "FDA" shall mean the United States Food and Drug Administration, or any successor entity having jurisdiction over the transactions contemplated by this Agreement.

1.12. The term "FDCA" shall mean the Federal Food, Drug and Cosmetic Act, 21 U.S.C. ss.ss.301-397, as amended.

1.13. The term "Force Majeure" shall mean any cause beyond the reasonable control of any non-performing party, including without limitation, , strikes, lockouts, inability to procure labor or material, fuels shortages, fires, explosions, earthquakes, riots, interference by civil or military authorities, terrorism, outbreak of war or insurgence, acts of war (declared or undeclared), sabotage, embargo, a national health emergency, or compliance with any order or regulation of any government entity acting with color of right.

1.14. The term "cGMPs" shall mean current good manufacturing practices for the methods to be used in, and the facilities and controls to be used for, the manufacture, testing, stability oversight, processing, packing and holding of drugs, as set forth in all applicable laws, rules and regulations in the Territory or as may otherwise be established by the FDA, including all amendments and supplements thereto, during the term of this Agreement.

1.15. The term "Health Registrations" shall mean the technical, medical and scientific licenses, registrations, authorizations and/or approvals of the Product (including the prerequisite manufacturing approvals or authorizations, marketing authorization based upon such approvals and pricing, Third Party reimbursement and labeling approvals related thereto) that are required by any national, regional, state or local regulatory agency, department, bureau or other governmental entity in the Territory, for the Manufacture, distribution, use or sale of Product in the Territory, as amended or supplemented from time to time, including, without limitation, an ANDA or NDA, for the Product, as amended or supplemented from time to time.

1.16. The term "Impax Know-How" shall mean the formulation for the Product, Impax's technology related to slow release and/or sustained release tablet dosage forms, Impax's ANDA for the Product (including the CMC portions thereof), and all other data, information, instructions, processes, procedures, assays and methods related to the Manufacture and/or testing of the Product which are owned or controlled by Impax as of the Effective Date.

1.17. The term "Initial Term" shall mean the period of time beginning on the Effective Date and ending ++ after the date of the first purchase of Product by Schering from Impax for sale in the Territory following receipt of Health Registration for the Product in the Territory.

1.18. The term "Intellectual Property" shall mean any patents, patent applications, trademarks, trademark applications, trade names, copyrights, trade secret rights, technology and all other intellectual property rights owned or controlled by a party that are related to the Product or the Manufacture or use thereof. With respect to Impax, Intellectual Property shall include, without limitation, the Impax Know-How and Impax's rights to any Inventions.

1.19. The term "Inventions" shall mean any inventions, discoveries, or innovations, whether patentable or not, relating to or arising out of the use of the Impax Know-How in connection with the development and/or Manufacture of the Product by Impax.

1.20. The term "Laws" shall mean all applicable federal, state or local statutes or laws, as well as all rules and regulations promulgated thereunder, by any Regulatory Authorities in the Territory, unless context requires otherwise. Any reference to a particular law or regulation will be interpreted to include any revision of or successor to such statute, law, rule or regulation regardless of how it is numbered or classified.

1.21. The term "Loss" shall mean claims, liabilities, costs, damages, losses, judgments for damages, or expenses (including reasonable attorneys' fees).

1.22. The term "Manufacture" "Manufactured" or "Manufacturing" shall mean all activities involved in the manufacture, packaging, handling, storage and testing of the Product in accordance with and pursuant to the terms of this Agreement.

1.23. The term "NDA" shall mean a new drug application filed with the FDA seeking approval to market and sell a new prescription or OTC pharmaceutical product in the Territory, and any such approvals granted by the FDA based upon such application.

1.24 The term "Orders" shall mean all quantities of the Product that shall be ordered by Schering for the Territory for research and development (including without limitation clinical trial materials), and for distribution, marketing (including samples), and sale of the Product in the Territory.

1.25. The term "Packaging Components" shall mean all materials and components used or incorporated in the final (primary and secondary) packaging of the Product for distribution and sale in the Territory.

1.26. The term "Product" shall mean a product containing the Active Pharmaceutical Ingredients in a twelve hour extended release tablet which is Manufactured in accordance with this Agreement and conforming to the Product Specifications as marketed as a product not requiring a prescription by a medical doctor or other health professional by Schering in the Territory.

1.27. The term "Product Specifications" shall mean the specifications and quality control testing procedures for the Product and as more fully set forth in Exhibit 1.27 hereto, as amended from time to time in accordance with the terms of this Agreement and consistent with the ANDA covering the Product.

1.28. The term "Proprietary Information" shall mean any scientific, technical, clinical, regulatory, marketing, financial or commercial information or data relating to the Product or the Manufacture or use thereof, that is disclosed by one Party to the other Party pursuant to this Agreement, or that is developed by a Party in the performance of its obligations under this Agreement.

1.29. The term "Price" shall mean the price as set forth on Exhibit 1.29 hereto for the Initial Term. After the Initial Term, the Price shall be determined as set forth in Section 6.1 hereof.

1.30. The term "Raw Materials" shall mean all raw materials, components, excipients, and Packaging Components, other than Active Pharmaceutical Ingredient, useful or necessary for the Manufacture of Product in accordance with this Agreement.

1.31. The term "Regulatory Authority" shall mean the applicable government regulatory authority in the Territory involved in granting the Health Registrations for the Product.

1.32. The term "Supply Failure" shall mean Impax's inability on more than two occasions during the Initial Term or on more than two occasions during any renewal period of this Agreement or any period subsequent to such failures to Manufacture enough Product pursuant to the forecasts referred to in Section 3.3 to deliver no later than the delivery date set forth in the purchase order at least seventy-five percent (75%) of the Product ordered by Schering for one calendar month.

1.33. The term "Territory" shall mean++.

1.34. The term "Third Party" shall mean any individual, corporation, trust, association, estate, partnership, joint venture, limited liability company, governmental entity or other legal entity other than Impax, Schering or their respective Affiliates.

ARTICLE II LICENSE FEE

2.1 License Fee. (a) In consideration of the initial fee and milestone payment set forth in this Section 2.1, Impax grants to Schering a non-exclusive license under Impax's ANDA, know-how and other intellectual property as they relate to the Product and the other rights granted to Schering under this Agreement including, but not limited to the rights to obtain supply of, market and distribute the Product, for the Initial Term and any renewal term of this Agreement.

(b) Within ten (10) business days of execution of this Agreement, Schering shall make an initial payment of ++ Dollars (\$ ++), provided, however, in the event that Impax does not receive tentative ANDA approval for the Product by January 1, 2003, Impax shall immediately reimburse Schering such initial fee. As soon as commercially reasonable after receipt of tentative ANDA approval, Impax shall purchase, install and qualify additional manufacturing machinery at a cost of at least ++ Dollars (\$++) for the purpose of increasing its capacity to produce the Product in accordance with its ANDA, as set forth on Exhibit 2.1(b).

++ Confidential portions omitted and filed separately with the Commission.

(c) Impax shall invoice Schering for its additional license payment of ++ Dollars (\$++) (the "Final License Payment") and Schering shall pay such amount with its payment of the initial invoice from Impax for the first commercial delivery of Product to Schering in accordance with this Agreement; provided, however, if the Product is not approved to be sold as Over-The Counter pharmaceutical product by the FDA ("OTC") in the Territory on or prior to January 1, 2003, Schering shall not be required to pay the Final License Payment until such approval has been granted. In the event that the Product has not been approved to be sold OTC by November 30, 2003, Schering shall have the right to terminate the Agreement, with no further obligations from either party, provided, however, Schering must pay for any product delivered pursuant to firm purchase orders issued in accordance with Section 3.4 hereof. In the event that Impax has received final ANDA approval, and Impax has fulfilled all of its obligations under the Agreement, but Schering has not placed a firm purchase order for Product by December 15, 2003, Schering shall pay Impax the Final License Payment on such date.

ARTICLE III SUPPLY OF PRODUCT

3.1 Supply of Product. Subject to the terms and conditions of this Agreement, Impax shall Manufacture and supply to Schering, and Schering shall purchase from Impax, the Product in accordance with Impax's ANDA and in amounts to be determined by Schering in its sole discretion (but no less than batch size quantities); provided that Schering shall be required to purchase a minimum of ++ tablets of the Product during the twelve (12) month period beginning with the first shipment of Product from Impax for commercial sale by Schering. Notwithstanding the other provisions of this Section 3.1, Schering shall not be subject to such minimum purchase requirements until Impax has received approval to sell its Product OTC. Schering shall prepay 75% of the initial order; provided, however, that such order shall not exceed Schering's initial three months' forecast of supply of Product. Nothing herein shall be construed as restricting or limiting Schering's right to manufacture the Product at Schering's or its Affiliate's facilities for use and/or sale in the Territory.

3.2 Supply of Raw Materials. Impax shall be responsible for procuring, at its own expense, the supply of all Raw Materials and Active Pharmaceutical Ingredient necessary for the Manufacture of Product in accordance with this Agreement. However, Schering shall have the right to supply or procure the supply of Active Pharmaceutical Ingredient at the fixed price to Impax set forth in Exhibit 3.1.

++ Confidential portions omitted and filed separately with the Commission.

3.3 Good Faith Forecasts. Impax represents that it can adequately supply Schering with Product in accordance with the preliminary non-binding forecast as set forth in Exhibit 3.3. Although the forecast on Exhibit 3.3 does not obligate Schering to make any purchases of Product, the parties acknowledge that it represents a good faith estimate of possible orders by Schering for Product during the Initial Term and any renewal term. Within thirty (30) days after the Effective Date, Schering shall provide Impax with a written twelve (12) month forecast estimating the amounts to be supplied by Impax under this Agreement, and the desired delivery dates therefor. Impax shall be obligated to provide Product up to 125% of the most recent forecast (and use Commercially Reasonable Efforts to provide Product in excess of 125% of the most recent forecast), upon receipt of a Purchase Order for such amount, as described in Section 3.4. Thereafter, on or before the first day of each month during the term hereof, Schering shall provide Impax with an updated written rolling forecast estimating Schering's purchases from Impax and the desired delivery dates therefor, for the succeeding twelve (12) month period. Such rolling forecasts shall include the forecast from the previously forecasted eleven (11) month period in addition to a forecast for the new month added. Such estimates shall be prepared in good faith, but shall not be binding on Schering, except that Schering shall place purchase orders for at least the quantity of products specified in the first three (3) months of each such rolling forecast. Schering shall not be responsible for any loss or expense incurred by Impax arising from such forecasts, except for such three (3) months' purchase orders. The obligation to give estimates is acknowledged by the parties to be a material provision of this Agreement. Accordingly, if Schering fails to give Impax an estimate after notice by Impax of such failure and Schering's continuing failure to provide an estimate to Impax, Impax and Schering shall discuss the reasons for Schering's failure and Impax will not decline to supply if Impax determines in its reasonable judgment that Schering has an adequate reason for its failure to furnish the estimate.

3.4 Purchase Orders. Schering shall issue to Impax firm purchase orders for each delivery, not later than twelve (12) weeks prior to the forecasted delivery date. In the event that Schering's initial purchase order for Product exceeds ++ tablets, Schering shall issue to Impax a firm purchase order not later than six (6) months prior to the forecasted delivery date. Schering shall be obligated to purchase, and Impax shall be obligated to sell, such quantities of the Product as are set forth in the purchase order, on the delivery schedule set forth therein with packaging initially to be either in bulk or in bottles of 1000 tablets pursuant to the approved ANDA for the Product. In the event that the terms of any such purchase order are not consistent with this Agreement, the terms of this Agreement shall prevail in the event that the amount of the purchase order exceeds 125% of the good faith forecast, then Impax shall make all Commercially Reasonable Efforts to modify its production schedule so as to deliver such additional quantities of Product to Schering as soon as practicable. Impax shall promptly confirm receipt of the purchase order as well as the delivery dates contained in the purchase order by written acknowledgment.

++ Confidential portions omitted and filed separately with the Commission.

Notwithstanding the foregoing, Schering may change firm purchase order dock dates, only if changed at least -four (4) weeks prior to the original firm purchase order dock date, but any costs incurred by Impax as a result of such change shall be borne by Schering (subject to approval of such costs by Schering, such approval not to be unreasonably withheld) . In addition, Impax will consider requests for changes to firm purchase order dock dates with less than four (4) weeks prior notice, but Impax is under no obligation to agree to such changes. Such dock date changes shall in no way reduce Schering's liability for such firm purchase orders. Also, Schering may change the Product Specifications of the Product, provided, however, that such changes shall in no way reduce Schering's liability for such firm purchase order, and further provided, that Schering shall be responsible for all costs associated with such change to the Product Specifications and, provided further, that Impax may delay delivery of Products which are the subject of a change in Product Specifications for such reasonable period of time to enable Impax to comply with the changed Product Specifications.

3.5 Stoppage Due to Good Cause. Upon Schering's written notice, Impax shall stop a scheduled production run of the Product, at no cost to Schering, provided that such request is based upon good cause. Good cause is defined as Impax's failure to comply, or its inability to assure compliance with cGMPs, Health Registrations or any other applicable Regulatory Authority requirements, rules or regulations. Exercise by Schering of its rights under this Section 4.4 shall not prejudice any other rights or remedies that Schering may have under this Agreement or otherwise at law or equity.

3.6 Stoppage At Schering's Discretion. Upon Schering's discretion and upon written notice, Impax shall stop a scheduled production run of the Product at no cost to Impax and Schering shall promptly reimburse Impax for any cost which Impax incurs as a result of such stoppage of production (subject to approval of such costs by Schering, such approval not to be unreasonably withheld).

3.7 Alternative Supply. Impax agrees to fully cooperate with Schering, at Schering's request and expense, to establish a back-up facility for the manufacture of the Product at one of Schering's, its Affiliate's or Third Party's manufacturing sites. Upon such request, Impax shall promptly initiate a complete technology transfer of the manufacturing process, procedures and standards used by Impax to Manufacture the Product so as to enable the back-up facility to manufacture the Product in accordance with the applicable Health Registrations for the Product. Impax and Schering shall use diligent efforts to ensure that the technology transfer is completed as soon as reasonably practicable. In the event that Schering decides to exercise its rights under this Section 3.7 and no Supply Failure or any other uncured material breach by Impax has occurred, Schering shall be obligated to pay Impax ++ per tablet of Product or tablet of Schering's existing proprietary D-12 formulation manufactured by or for Schering for sale in the Territory

++ Confidential portions omitted and filed separately with the Commission.

during the Agreement; provided, however, Schering shall not be obligated to pay Impax for any Schering proprietary D-12 formulation product manufactured by Schering prior to the first shipment by Impax of Product to Schering for commercial sale in accordance with the Agreement.

Any such payments due under this Section 3.7 shall be paid to Impax within sixty (60) days of the close of each calendar quarter within which the tablets were manufactured and shall be accompanied by a statement detailing the number of tablets manufactured and the calculation of the payment owed to Impax. Schering shall keep records in sufficient detail to enable Impax to verify the calculation of the number of tablets of Product manufactured during each quarter. Impax has the right, at its discretion and expense, but not more frequently than one (1) time per calendar year, to inspect, during ordinary business hours of Schering, records as may be necessary to verify Schering's calculation of any payment due under this Section 3.7.

3.8 Capacity. Upon receipt of the forecasts provided for in Section 3.3, Impax shall confirm its ability to meet such demand with existing capacity. If Impax confirms that it is unable to meet such Schering forecast, the parties agree to negotiate revised forecasts or add capacity as set forth below. Impax further agrees that any funding for additional capacity to support the manufacture of the Product in accordance with the Agreement shall be born solely by Impax; provided, however, in the event that such forecasts require capacity in excess of existing capacity and such forecasts exceed by more than 25% the forecasts shown on Exhibit 3.3, Schering and Impax shall share equally in the documented costs to add such capacity.

ARTICLE IV

DEVELOPMENT ACTIVITIES

4.1 Impax's Obligation. (a) Impax shall be responsible, at its expense, for all development and regulatory activities performed by or on behalf of Impax in connection with the preparation, filing and maintenance of the ANDA for the Product.

(b) At Schering's option and expense, but subject to Impax's Manufacturing and Product development capabilities and capacity, Impax shall perform all development and regulatory activities agreed upon by the parties beyond those activities required by Section 4.1(a).

(c) Impax shall use its Commercially Reasonable Efforts to accelerate its development, Manufacturing and regulatory activities related to the Product to enable it to supply Product to Schering for sale in the Territory as soon as is reasonably practicable.

(d) Subject to Section 3.8 hereof, Impax shall also purchase the necessary equipment and take all other necessary steps to enable it to supply Schering's Orders for the Products.

(e) Impax shall provide 300,000 tablets (in two deliveries of 150,000 tablets each) to be manufactured for stability testing purposes for currently unsubmitted bulk drum and blister packages; and Impax shall further provide stability testing services in support of commercialization of the Product in such packages.

4.2. Cost Reductions. The parties shall work together to develop cost reductions, but the foregoing does not constitute a guarantee by Impax of any cost reductions. Both parties agree that cost reductions may be possible by improvements in the technology for Manufacturing or by negotiating with regulatory authorities to achieve cost effective product specifications or by changes in regulatory standards applicable to manufacturing, among other reasons. Any such cost reduction program shall be expressly agreed to in writing by Impax and Schering prior to implementation and prior to any reduction in the price of the Product hereunder. In the event a cost reduction program is accepted, both parties agree to a sharing plan based upon the following conceptual guidelines:

a) Any cost savings initiated by Schering related to independently negotiated material pricing, formula change or packaging changes shall be to Schering's sole benefit.

b) Any cost savings resulting from process changes initiated by Impax shall be allocated 75% to Impax and 25% to Schering.

c) Any Raw Material cost savings resulting from joint sourcing strategies/synergies or by Impax sourcing activities shall be negotiated and shared with no less than 50% of such savings allocated to Schering.

ARTICLE V DELIVERY AND RELATED MATTERS

5.1 Certificate of Analysis. Impax shall provide Schering with each shipment of Product a certificate from Impax's quality assurance department that includes the results of quality control testing in accordance with the Product Specifications and which indicates that the Product contained in the shipment meets the Product Specifications. Impax shall also notify Schering in writing of the specific storage conditions and any special handling procedures for the Product.

5.2 Risk of Loss. Delivery of each shipment of the Product shall be made FCA. Impax shall arrange for transportation of the Product to a destination designated by Schering and by a common carrier designated by Schering. Title to and risk of loss of the Product shall pass to Schering at the time of delivery to the carrier. Impax shall promptly invoice Schering for all Product shipped.

5.3 Storage. Impax, at its own expense, shall maintain adequate and appropriately segregated facilities in accordance with cGMPs and Health Registrations at the Approved Facilities for storage of the Product pending delivery to the designated carrier pursuant to Section 5.2 hereof.

5.4 Delay and Failure to Supply.

(a) In the event that Impax shall have reason to believe that it will be unable to supply Schering with the full quantity of the Product forecasted to be ordered or actually ordered by Schering in a timely manner, Impax shall promptly (and in any event within five (5) business days) notify Schering thereof. If Impax shall so notify Schering, or if Impax shall fail to provide Schering with adequate assurances of timely performance upon Schering's request therefor (regardless of whether past performance has complied herewith or not), Schering and Impax shall promptly meet to discuss how to thereafter supply Product in a timely manner. If, however, Schering at any time determines in the exercise of its reasonable judgment that there will be a Supply Failure or that there is a Supply Failure, Schering or an Affiliate of Schering may (but shall not be obligated to) Manufacture such quantity of the Product or its equivalent that Impax is unable to produce or, alternatively, Schering may enter into a supply agreement with a Third Party to manufacture such quantity of the Product or its equivalent that Impax is unable to provide (taking into account minimum batch sizes and pricing efficiencies of such supplier), upon such terms and conditions as Schering shall determine in its sole discretion, whereupon Schering's purchase obligation under Article IV hereof shall be adjusted accordingly. If the Cure Price for the Supply Failure is in excess of the Price, Schering shall invoice Impax for an amount equal to the excess of the Cure Price over the Price and provide reasonable documentation evidencing the Cure Price to Impax with such invoice. Impax shall pay such invoice within 30 days and such payment obligation shall constitute Impax's sole and exclusive liability for claims under this Section 5.4.

(b) In the event that any Supply Failure shall be caused by a Force Majeure, Schering or an Affiliate of Schering may (but shall not be obligated to) Manufacture the Product or, alternatively, Schering may enter into a supply agreement with a Third Party to purchase such quantity of Product or its equivalent that Impax is unable to produce, upon such terms and conditions as Schering shall determine in its sole discretion, whereupon Schering's purchase obligation under Article IV hereof shall be adjusted accordingly and Impax shall not be required to pay the Cure Price.

(c) In the event of a Supply Failure under Section 5.4 (a) or

(b) above, Impax shall exercise Commercially Reasonable Efforts to resume production as quickly as possible and shall notify Schering in writing upon resumption of production, whereupon it shall supply Schering with Product with such modified requirements for the Product as Schering may have for the remaining term of this Agreement.

(d) The failure by Impax on more than two occasions during the Initial Term or on more than two occasions during any renewal period of this Agreement or any period subsequent to such failures to fill in a timely manner at least 75% of any delivery specified on a purchase order placed by Schering pursuant to Article IV of this Agreement shall, subject to the terms of Section 16.2, be a material breach of this Agreement.

5.5 Rejection. If Schering claims that any shipment of Product did not, at the time of delivery to the carrier designated by Schering, meet the warranties in Section 12.2(b), (c), (d), (e)(ii), e(v) or (f) or that Impax did not comply with the covenants in Section 12.1, Schering shall notify Impax. If Impax agrees with Schering's claim, Impax at its option shall either promptly replace such Product or reimburse Schering for any payment Schering may have made to Impax for such Product and for any out-of-pocket expense Schering may have incurred with respect thereto prior to Schering's discovery of the defect, including without limitation shipping, insurance, taxes, and if applicable, packaging costs. If Schering and Impax are unable to agree as to whether such Product met the warranties or whether Impax complied with the covenants, the parties shall cooperate to have the Product in dispute analyzed by an independent Third Party testing laboratory of recognized repute jointly selected by Schering and Impax. If the Product is determined by such Third Party to meet the Product Specifications, then Schering shall bear the cost of the independent laboratory testing and pay for the Product in accordance with this Agreement. If the Product is determined not to have met the Product Specifications at time of delivery, then Impax shall bear the cost of the independent laboratory testing, and Impax shall, at Schering's election, either replace the rejected Product as soon as possible but no later than within sixty (60) days after the date of such determination, at no cost to Schering, or refund or credit, as designated by Schering, the price paid for such Product plus any applicable delivery charge, within sixty (60) days after written notice from Schering. Such laboratory costs, refund, credit or replacement shall constitute Impax's sole and exclusive liability for claims under this Section 5.5.

ARTICLE VI PAYMENT

6.1 Price. The Price to be paid by Schering to Impax for the Product during the Initial Term shall be as set forth on Exhibit 1.29 hereto, and shall

be made in United States dollars within thirty (30) days from date of receipt of invoice therefor for Product received by Schering. After the Initial Term, the Price to be paid by Schering to Impax for the Product may be increased for any increase in the United States Consumer Price Index for material, labor and overhead costs during the immediate preceding year (excluding the fixed costs set forth in Exhibit 1.29), but in no event shall such cost increase by more than a total of three percent (3%) for such year over the Price at the end of the immediate preceding year.

6.2 Taxes. Impax and Schering agree to cooperate in order to minimize, in the manner permitted under applicable tax and customs laws and regulations, the taxes (including value-added taxes) and duties associated with the importation and/or exportation of the Active Pharmaceutical Ingredient and the Product, as the case may be.

ARTICLE VII

APPROVAL SUPPORT; REGULATORY MATTERS

7.1 Approval Support. Impax shall produce stability batches and validation batches, engage in various development activities and perform various tests as necessary for receipt of the Health Registrations in the Territory, including without limitation, being prepared for the pre-approval inspections by the Regulatory Authorities and performing the other activities set forth in Exhibit 7.1 hereto.

7.2 Filing and Maintenance of the Health Registrations. Impax shall be responsible for the preparation, filing and maintenance of the ANDA for the Product, including without limitation the CMC sections and shall promptly undertake to qualify bulk supply of Product in drums. In the event Impax subsequently modifies any relevant Health Registration (or the CMC) for which it is responsible, it shall promptly notify Schering and provide it with copies of such Health Registration (or CMC) supplements or amendments.

7.3 Specifications Amendments. Except to the extent specifically required by relevant Health Authorities, Impax shall not modify the Product Specifications without Schering's prior written approval, such approval not to be unreasonably withheld.

7.4 Impax Approvals. Except as otherwise specifically set forth herein, Impax shall be responsible for obtaining and maintaining all approvals from the Regulatory Authorities and any other governmental authorities required in connection with the performance of its obligations hereunder.

7.5 Complaints As soon as practical after the Effective Date (and in any event within one hundred twenty (120) days), Impax and Schering shall negotiate in good faith and agree upon mutually acceptable guidelines and procedures for investigating, responding to and reporting product complaints.

Notwithstanding any provisions of Section 7.5 and 7.6, Impax is not relieved of any of its responsibilities as the ANDA holder of the Product. Accordingly, Impax shall perform all of its obligations in compliance with all applicable laws, rules and regulations, including without limitation, FDA regulations.

7.6 Adverse Events. As soon as practical after the Effective Date (and in any event within one hundred twenty (120) days), Impax and Schering shall negotiate in good faith and agree upon mutually acceptable guidelines and procedures for adverse drug event information exchange and reporting.

ARTICLE VIII

QUALITY CONTROL AND REGULATORY COMPLIANCE

8.1 Facility Compliance and Related Matters. Impax shall maintain the Approved Facility and shall conduct all Manufacturing in compliance with all applicable laws, rules and regulations, including cGMPs, and the Impax Know-How at all times during the term of this Agreement. Impax shall be responsible for all costs and expenses related to the compliance of the Approved Facility with such laws, rules and regulations and with the Impax Know-How. Impax agrees to Manufacture the Product at the Approved Facility, and not to change the location thereof without Schering's prior written consent.

8.2 Quality Control Program. Impax shall maintain a quality control program consistent with cGMPs, as required by the applicable Regulatory Authorities in the Territory. Impax shall, within thirty (30) days of the Effective Date, provide Schering with a written summary description of such program establishing that it has met such cGMPs, which may be amended or supplemented from time to time; provided that Impax gives Schering prompt written notice of such amendments or supplements.

Impax shall have sole responsibility for quality control testing of each batch of Product supplied to Schering hereunder to ensure that such Product meets the Product Specifications. Impax shall retain records of all such testing, copies of which shall be provided to Schering upon written request. Impax shall provide Schering with a certificate of analysis for each batch of Product. Schering shall have the right to test Product to verify compliance with the applicable Product Specifications, at its expense.

8.3 Approval for Third Party Manufacturing. Impax agrees not to contract with any Third Party to conduct part or all of the Manufacturing of the Product without the prior written consent of Schering, which consent can be withdrawn at any time. Impax further agrees not to contract with any Third Party, other than those listed on its ANDA, to conduct part or all of the testing of the Product without the prior written consent of Schering, such consent not to be unreasonably withheld, but which consent can be withdrawn upon at least six (6) months prior notice.

8.4 Retention of Samples. Impax shall retain a sufficient quantity of each batch of Product to perform at least two full sets of quality control tests (which shall be in addition to the quality control testing performed by Impax prior to delivery). Impax shall maintain samples of each batch in a suitable environmentally controlled storage facility until at least the first anniversary of the end of the approved shelf life of all Product from such batch, or such longer period as may be required under applicable law, regulation or rule. All such samples shall be available for inspection and testing by Schering or a Third Party chosen by Schering at its sole discretion, including but not limited to any Affiliate, upon reasonable notice.

8.5 Batch Failure. Impax agrees to notify Schering within thirty-six (36) hours of discovery after any batch failure which could result in Impax's inability to meet Schering's requested delivery dates, or of learning of any failure of any batch of Product to meet standards set forth in the Impax Know-How. Impax shall notify Schering within thirty-six (36) hours after any failure of a released batch during stability testing. Impax shall complete out-of-specification investigations within thirty (30) calendar days from date of discovery.

8.6 Notification of Regulatory Inspections. Impax agrees to notify Schering within thirty-six (36) hours after the initiation of any inquiries, notifications, or inspection activity by any Regulatory Authority in regard to the Product or the Approved Facility. In furtherance and not in limitation of the foregoing, Impax shall notify Schering prior to the commencement of any inspection activity by any Regulatory Authority regarding the Product or any general cGMP inspection, unless such inspection activity is an unannounced inspection. Further, Impax shall provide a reasonable description to Schering of any such governmental inquiries, notifications or inspections promptly (but in no event later than two (2) calendar days) after such visit or inquiry. Impax shall furnish to Schering, (a) within two (2) days after receipt, any report or correspondence issued by the Regulatory Authority in connection with such visit or inquiry, including but not limited to, any FDA Form 483, Establishment Inspection Report, or warning letter, or other regulatory communications and (b) copies of any and all responses or explanations to any Regulatory Authority relating to items set forth above, in each case purged only of trade secrets of Impax that are unrelated to its obligations under this Agreement and are unrelated to the Product, prior to the submission of such responses or explanations to any Regulatory Authority by Impax.

8.7 Inspection by Schering. Schering shall have the right, during normal business hours (and after normal business hours if reasonably requested and in connection with a production run commenced during the normal business hours) and with reasonable advance notice, to visit the Approved Facility for the purpose of observing the Manufacturing, packaging, testing, and storage of the Product, and to inspect for compliance to cGMPs and other applicable regulatory requirements. Impax's quality assurance department shall cooperate

with Schering, as necessary and useful, in any inspection conducted pursuant to this Section 8.7, and resolve any open observations to Schering's satisfaction. Further, Impax shall maintain records of its involvement with any inspection in accordance with its customary business practices, as long as such practices satisfy the recordkeeping requirements set forth in Section 15.2 hereof.

8.8 Environmental and Other Laws and Regulations. In carrying out its obligations under this Agreement, Impax shall have sole responsibility for compliance with all applicable Laws, including without limitation environmental and health and safety laws, as amended from time to time. Impax shall immediately notify Schering in writing of any event, including the receipt of any notice, warning, citation, finding, report or service of process or the occurrence of any release, spill, upset, or discharge of hazardous wastes or substances, relating to the Manufacture of the Product that may give rise to liability on the part of Impax under the Laws or this Agreement. Schering reserves the right to conduct an environmental inspection of Impax's facility, during normal business hours and with reasonable advance notice, for the purpose of determining compliance with this Section 8.8. Schering shall share the results of any such environmental inspection with Impax. Such inspection, if any, shall not relieve Impax of its sole obligation to comply with the Laws and does not constitute a waiver of any right otherwise available to Schering.

ARTICLE IX PRODUCT RECALL

9.1 Notification and Recall. In the event that any Regulatory Authority issues or requests a recall or takes similar action in connection with the Product, or in the event either party hereto determines an event, incident or circumstance has occurred that may result in the need for a recall or market withdrawal, the party notified of or determining the need for such recall or similar action shall, within twenty-four (24) hours, advise the other party thereof by telephone or facsimile. Following notification of a recall, within forty-eight (48) hours, the parties shall discuss whether or not to conduct a recall, and if so, the timing of the recall, the breadth, extent and level of customer to which the recall shall reach, the strategies and notifications to be used, and other related issues. In the event that the parties cannot agree on any such decision, the issue shall be resolved by Schering.

9.2 Recall Expenses. Impax shall bear the expenses of any recall resulting from a breach of its obligations hereunder. Such expenses of recall shall include, without limitation and without duplication, the expenses of notification and destruction or return of the recalled Product, the sum paid by Schering to Impax for the Manufacture of the recalled Products, Schering's costs relating to the testing, packaging, shipping, and retail trade related costs of the recalled Products and the cost to Schering for the Active Pharmaceutical Ingredient and other Raw Materials or Packaging Components supplied by Schering and used in the Manufacture of the recalled Products and not paid for by Impax, and any Losses caused by, arising out of, or resulting from such recall. The rights of Schering under this Section 9.2 shall be Schering's sole remedy under this Agreement or at law for such recall.

ARTICLE X
INTELLECTUAL PROPERTY RIGHTS

10.1 Intellectual Property Rights. (a) Schering shall own all right, title to and interest in the Intellectual Property of Schering or derivatives thereof developed by or on behalf of Schering in performance of this Agreement. In no case, except as provided explicitly herein, whether during the term of this Agreement or upon expiration or any termination thereof, shall Impax or any Third Party be deemed to have or be entitled to any right or license to any Intellectual Property of Schering or any Intellectual Property controlled or licensed by Schering. Impax shall provide Schering with reasonable assistance in executing and filing any documents necessary to evidence Schering's ownership of its Intellectual Property, including, without limitation, executing any assignments or providing assistance with filing for and maintaining patents with respect to the Intellectual Property of Schering.

(b) Impax shall own all right, title to and interest in the Intellectual Property of Impax or derivatives thereof developed by or on behalf of Impax in performance of this Agreement. In no case, except as provided explicitly herein, whether during the term of this Agreement or upon expiration or any termination thereof, shall Schering or any Third Party be deemed to have or be entitled to any right or license to any Intellectual Property of Impax or any Intellectual Property controlled or licensed by Impax. Schering shall provide Impax with reasonable assistance in executing and filing any documents necessary to evidence Impax's ownership of its Intellectual Property, including, without limitation, executing any assignments or providing assistance with filing for and maintaining patents with respect to the Intellectual Property of Impax.

(c) During the term of this Agreement, in the event that Impax develops, discovers or creates any Inventions relating to the Product or the Manufacture and use thereof, such Inventions shall be the sole property of Impax.

10.2. ++ .

10.3. Trademarks and Trade Names. Schering and Impax hereby acknowledge that neither party has, nor shall either party acquire by reason of this Agreement, any interest or rights of use in any of the other party's trademarks, trade names, trade dress, designs or logos unless otherwise expressly agreed in writing between the parties hereto.

++ Confidential portions omitted and filed separately with the Commission.

ARTICLE XI
TERM AND TERMINATION

11.1 Term. This Agreement shall terminate upon the expiration of the Initial Term, unless sooner terminated by one of the parties in accordance with this Article XI or unless renewed pursuant to Section 11.5 below.

11.2 Termination by Schering.(a) Schering shall have the right to terminate this Agreement upon ninety (90) days' prior notice to Impax if:

(i) Impax is subject to any Regulatory Authority warning letter or sanction, which is general in nature or relates specifically to the Product, and which is not conclusively resolved between Impax and the Regulatory Authority within one hundred eighty (180) days of issue; provided, however, that Impax must diligently pursue resolution of such warning letter or sanction during such period;

(ii) there is a change in control of Impax. For purposes of this provision, a "change in control" shall mean the acquisition of direct or indirect ownership of over fifty percent (50%) of the outstanding voting securities of Impax, or actual control over the management, business and affairs of Impax, by a non-Affiliate thereof; or

(iii) Impax files a petition in bankruptcy, or enters into an arrangement with its creditors, or applies for or consents to the appointment of a receiver or trustee, or makes an assignment for the benefit of creditors, or suffers or permits the entry of an order adjudicating it to be bankrupt or insolvent. In the event this Agreement is terminated under this Section 11.2(iii), all rights and licenses granted pursuant to Section 10.2 of this Agreement by Impax to Schering are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101(52) of the Bankruptcy Code. The parties agree that Schering, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code. The parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against Impax under the Bankruptcy Code, Schering shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property upon written request therefor by Schering. Such intellectual property and all embodiments thereof shall be promptly delivered to Schering (i) upon any such commencement of a bankruptcy proceeding upon written request therefor by Schering, unless Impax elects to continue to perform all of its obligations under this Agreement or (ii) if not delivered under (i) above, upon the rejection of this Agreement by or on behalf of Impax upon written request therefor by Schering.

(b) Either party shall have the right to terminate this Agreement on or after January 1, 2003, if Impax has not yet received tentative ANDA approval by January 1, 2003.

11.3 Termination for Material Default. (a) Except for a breach under

Section 11.3(b) hereof, upon default by a party in the performance of any material obligation under this Agreement, the non-defaulting party shall give notice in writing to the party in default and the defaulting party shall have sixty (60) days thereafter to cure the default. The defaulting party shall, immediately upon receipt of such notice, take diligent steps to cure such default. If the defaulting party does not cure or institute measures to substantially cure such default within thirty (30) days and diligently complete the cure within an additional thirty (30) days (unless such thirty (30) day period is not a sufficient period of time to cure such default, in which event the defaulting party shall have up to an additional 30 days to cure such default), the non-defaulting party may terminate this Agreement by providing written notice of intent to terminate which shall take effect ten (10) days following the receipt by the defaulting party of such notice.

(b) Impax recognizes that, in the absence of this Agreement, it would be barred by applicable laws and regulations from making, using, selling, offering to sell or importing within the United States the loratadine product defined by ANDA 76-050, prior to the earlier of July 25, 2003 or a decision by the New Jersey District Court in Civil Action No. 01-0279 holding that Claims 1 and 3 of U.S. Patent No. 4,659,716 are invalid, unenforceable or not infringed by such product. Accordingly, it shall constitute a material breach of this Agreement in the event that Impax, prior to the earlier of July 25, 2003 or a decision by the New Jersey District Court in Civil Action No. 01-0279 holding that Claims 1 and 3 of U.S. Patent No. 4,659,716 are invalid, unenforceable or not infringed by such product, undertakes to, or actually, , sells or distributes within the United States the loratadine product defined by ANDA 76-050 for any purpose other than supplying Schering under the terms of this Agreement (hereinafter "Prohibited Actions"). Impax stipulates and agrees that such Prohibited Actions and material breach of this Agreement would: (1) not be subject to the provisions of Section 11.3(a) of this Agreement; (2) cause Schering immediate, irreparable harm for which monetary damages would not be adequate compensation; and (3) entitle Schering to obtain a temporary restraining order, and injunction enjoining such Prohibited Actions.

11.4 Effect of Termination. Expiration or termination of this Agreement shall not relieve the parties of any obligation accruing prior to such expiration or termination, and the provisions of Sections 7.5, 7.6, 8.4, 8.6, 11.4, 11.6 and 16.8 hereof and Articles IX, X, XII, XIII, XIV and XV hereof shall survive the expiration or termination of this Agreement. Any expiration or early termination of this Agreement shall be without prejudice to the rights of either party against the other accrued or accruing under this Agreement prior to termination.

11.5 Option to Renew. So long as Schering is not in breach of this Agreement, the term of this Agreement may be extended for an additional term of

++ at Schering's option, in accordance with the same terms of this Agreement; provided however that the Active Ingredient Prices for the renewal period shall be as set forth on Exhibit 3.1 hereof. In the event that Schering, in its sole discretion, wishes to extend the term of this Agreement it shall provide written notice to that effect to Impax at least one hundred and eighty (180) days prior to the end of the Initial Term. Impax shall respond in writing to such notice within thirty (30) days, acknowledging the extension of the term of the Agreement. If Schering elects not to extend the Agreement, then the Agreement shall expire at the end of the Initial Term.

11.6 Right to Manufacture. Notwithstanding any other provisions of this Agreement, in the event that Impax has an uncured material breach in accordance with Section 11.3 hereof, Schering shall have the right to manufacture the Product or have the Product manufactured by a Third Party in accordance with the Agreement, with no further payment obligations to Impax for any amounts relating to such manufactured Product.

ARTICLE XII COVENANTS; REPRESENTATIONS AND WARRANTIES

12.1 Impax's Covenants. Impax covenants that,

(a) at the time of delivery of the Product to the designated carrier pursuant to Section 5.2 hereof, the Product shall:

(i) have been Manufactured, tested, stored and shipped and had stability oversight conducted in accordance with applicable cGMPs and all other applicable laws, rules, regulations or requirements of Regulatory Authorities in the Territory;

(ii) have been Manufactured in accordance with the Impax Know-How, including without limitation the Product Specifications and the CMC;

(iii) not be adulterated or misbranded under the FDCA or the Laws;

(iv) have been Manufactured no more than two (2) months (if shipment in bulk) or three (3) months (if shipment in bottles) prior to delivery to the designated carrier pursuant to Section 5.2 hereof; and

++ Confidential portions omitted and filed separately with the Commission.

(v) be in good, usable and merchantable condition and fit for its intended purpose.

(b) it will have good and marketable title, free and clear of any liability, pledge, lien, restriction, claim, charge, security interest or other encumbrance, to all Product delivered to the designated carrier pursuant to Section 5.2 hereof;

(c) it will not use in any capacity, in connection with the services to be performed under this Agreement, any person who has been debarred pursuant to Section 306 of the FDCA (codified at 21 U.S.C.ss.335a), or who is the subject of a conviction described in such section;

(d) it will inform Schering in writing immediately if it or any person who is performing services hereunder is debarred or is the subject of a conviction described in Section 306 of the FDCA, or if any action, suit, claim, investigation, or legal or administrative proceeding is pending or, to the best of Impax's knowledge, is threatened, relating to the debarment or conviction of Impax or any person performing services hereunder; and

(e) it will promptly notify Schering in writing of any material adverse change in the business of Impax which could affect Impax's ability to perform its obligations under this Agreement.

(f) it will not , sell or distributewithin the United States, loratadine for the purpose of commercially marketing a loratadine product under ANDA 76-050, outside of supplying Schering under the license granted under this agreement (hereinafter "prohibited actions") prior to the earlier of July 25, 2003 or a decision by the New Jersey District Court in Civil Action No. 01-0279 holding that claims 1 and 3 of U.S. Patent No. 4,659,716 are invalid, unenforceable or not infringed by the product defined by ANDA 76-050.

12.2 Impax's Representations and Warranties. Impax represents and warrants to Schering that,

(a) it has the financial resources, appropriate skills, personnel, equipment, permits, and approvals necessary or useful to perform its obligations under this Agreement in compliance with the Laws;

(b) it owns, or is licensed with the right to sublicense, all Intellectual Property rights (including without limitation the Impax Know-How) necessary or useful to Manufacture the Product;

(c) to the best of its knowledge as of the Effective Date, the Impax Intellectual Property does not infringe the Intellectual Property rights of any Third Party;

(d) it is not aware of any Third Party infringement of its Intellectual Property rights;

(e) no material adverse change has occurred within the past six (6) months, with respect to Impax and its operations including without limitation material changes in or to its;

(i) insurance coverage;

(ii) threatened or pending legal claims affecting the Product;

(iii) labor pool;

(iv) suppliers;

(v) quality assurance systems; or

(vi) key personnel;

(f) it has good and marketable title to and/or right to use, the equipment and other assets useful or necessary to Manufacture the Product at the Approved Facilities;

(g) it has adequate capacity to meet Schering's initial forecast as set forth on Exhibit 3.3, its own requirements for Product and the requirements of any other purchasers of Product that Impax chooses to sell Product.

12.3 Representations and Warranties of Schering. Schering hereby further represents and warrants to Impax that:

(a) Schering has not and will not, enter into any agreement or any other transaction with any third party or Affiliate that impedes Schering's obligations under this Agreement; provided, however, that Impax acknowledges that Schering is in the business of developing, manufacturing and selling pharmaceutical products and nothing in this Agreement shall be construed as restricting such business.

(b) In the event that Schering and/or its Affiliates shall manufacture a product pursuant to Section 5.4(a), all such product shall (a) meet the applicable Specifications at the time of shipment, (b) meet all regulatory requirements of any relevant Regulatory Authority in the Territory, (c) be manufactured, packaged, tested, stored and shipped in accordance with Regulatory Approval and all Laws, (d) not be adulterated or misbranded under the FDCA or relevant laws and regulations and (e) be produced, packaged and tested and stored in environmentally controlled facilities that have been approved by the applicable Regulatory Authority to the extent required by Law.

(c) In the event and to the extent that Schering and/or its Affiliates shall manufacture a product pursuant to Section 5.4(a), Schering's and/or its Affiliates' manufacturing facilities for such product shall conform in all respects to Laws governing such facilities.

(d) Neither Schering nor any of its Affiliates shall have been debarred or is subject to debarment and will not use in any capacity, in connection with the services to be performed under this Agreement, any Person who has been debarred pursuant to Section 306 of the FDCA or is the subject of a conviction described in such section, and

(e) All Product which Schering shall package, test, store, ship or market under this Agreement shall have been marketed and stored in accordance with Regulatory Approval and all Laws.

12.4. Impax's and Schering's Representations and Warranties. Each of Impax and Schering hereby represents and warrants to the other as follows:

(a) it is a corporation duly organized and validly existing under the laws of the state or other jurisdiction in which it is incorporated;

(b) the execution, delivery and performance of this Agreement by such party has been duly authorized by all requisite corporate action;

(c) it has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder;

(d) the execution, delivery and performance by such party of this Agreement and its compliance with the terms hereof does not and will not conflict with or result in a breach of any term of, or constitute a default under (i) any agreement or instrument binding or affecting it or its property;

(ii) its charter documents or bylaws; or (iii) any order, writ, injunction or decree of any court or governmental authority entered against it or by which any of its property is bound;

(e) it has obtained any consent, approval or authorization of, or notice, declaration, filing or registration with, any governmental or Regulatory Authority required for the execution, delivery and performance of this Agreement by such party, and the execution, delivery and performance of this Agreement will not violate any law, rule or regulation applicable to such party;

(f) this Agreement has been duly executed and delivered and constitutes such party's legal, valid and binding obligation enforceable against it in accordance with its terms subject, as to enforcement, to bankruptcy, insolvency, reorganization and other laws of general applicability relating to or affecting creditors' rights and to the availability of particular remedies under general equity principles; and

(g) it shall comply with all applicable laws, rules and regulations relating to its performance under this Agreement.

12.5. EXCEPT AS OTHERWISE SPECIFICALLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY WARRANTY OF ANY KIND, EXPRESS OR IMPLIED.

ARTICLE XIII INDEMNIFICATION AND INSURANCE

13.1 Impax's Indemnification Obligation. Impax shall indemnify, defend and hold Schering, its Affiliates and each of its and their respective employees, officers, directors and agents harmless from and against all Losses caused by, arising out of, or resulting from: (a) Impax's breach of this Agreement; or (b) any infringement of Third Party patents by Impax's use of its Intellectual Property for the Manufacture of the Product or by Schering's use of Impax's Intellectual Property as licensed hereunder, in each case except to the extent caused by the negligence or intentional misconduct of Schering.

13.2 Schering's Indemnification Obligation. Schering shall indemnify, defend and hold Impax, its Affiliates and each of its and their respective employees, officers, directors and agents harmless from and against all Losses caused by, arising out of, or resulting from: (a) Schering's breach of this Agreement; or (b) the marketing, packaging, storage, shipment and sale of Product in the Territory by Schering, in each case except to the extent caused by the negligence or intentional misconduct of Impax.

13.3 Conditions to Indemnification. (a) The indemnified party shall give the indemnifying party prompt written notice of (i) the institution of any suit against the indemnified party for which it may seek indemnification under this Article XIII and (ii) any claims, including any claims asserted or made by any Regulatory Authority having jurisdiction, against the indemnified party for which it may seek indemnification under this Article XIII. The failure to give such notice shall not relieve the indemnifying party from any liability that it may have to the indemnified party under this Article XIII except to the extent that the indemnifying party's ability to defend such suit or claim is materially prejudiced by the failure to give such notice. The indemnifying party shall be entitled to participate in the defense of such suit or claim and to assume control of such defense; provided, however, that if it assumes such defense:

(i) the indemnified party shall be entitled to participate in the defense of such claim and to employ counsel at its own expense to assist in the handling of such claim;

(ii) the indemnifying party shall obtain the prior written approval of the indemnified party before entering into any settlement of such claim or ceasing to defend against such claim, if, pursuant to or as a result of such settlement or cessation, injunctive or other equitable relief would be imposed against the indemnified party; and

(iii) the indemnifying party shall not consent to the entry of any judgment or enter into any settlement that does not include as an unconditional term thereof the giving by the claimant or plaintiff to each indemnified party of a release from liability in respect of such claim.

Notwithstanding the foregoing, the indemnified party shall be entitled to have sole control at its own expense over the defense or settlement of any suit or claim to the extent the suit or claim could materially adversely affect the business, operations, assets, condition or prospects of the indemnified party and the indemnifying party shall be entitled to participate at its own expense in such defense or settlement.

(b) After written notice by the indemnifying party to the indemnified party of its election to assume control of the defense of any such action, the indemnifying party shall not be liable to such indemnified party hereunder for any legal fees and expenses subsequently incurred by such indemnified party in connection with the defense thereof. If the indemnifying party does not assume control of the defense of such claims as provided in this Section 13.3(b), the indemnified party shall have the right to defend such claim in such manner as it may deem appropriate at the cost and expense of the indemnifying party, and the indemnifying party shall promptly reimburse the indemnified party therefor in accordance with this Section 13.3(b). The reimbursement of fees, costs and expenses required by this Section 13.3(b) shall be made by periodic payments during the course of the investigation or defense, as and when bills are received or expenses incurred. The indemnified party shall provide to the indemnifying party, as promptly as practicable after any claim for indemnification hereunder, such information and documentation as may be reasonably requested by the indemnifying party to support and verify the claim asserted, so long as such disclosure would not violate the attorney-client privilege of the indemnified party.

13.4 Insurance. Impax represents and warrants that during the term of this Agreement, it shall maintain the types and amounts of insurance set forth below:

(a) general liability insurance, including contractual liability coverage of all of Impax's obligations under this Agreement and products liability/completed operations coverage with a minimum limit of ten million dollars (\$10,000,000).

(b) Such insurance shall be evidenced by a certificate of insurance which shall provide that Schering shall receive thirty (30) days' prior written notice of cancellation or material change of such policy.

13.4 Exclusion. Notwithstanding any provision of this Agreement to the contrary, in no event shall either party be liable to the other under this Agreement for any incidental, consequential, punitive or special damages, including without limitation loss of profit or revenues; provided, however, such limitation shall not apply to lawsuits, claims, actions or proceedings instituted by a Third Party against a party hereto, which are caused (directly or indirectly) by facts or circumstances constituting a breach of this Agreement by the other party.

ARTICLE XIV CONFIDENTIALITY

14.1 Confidentiality. 14.1 Impax and Schering acknowledge that each party considers its Proprietary Information to be of significant value and that such information shall be maintained as confidential. Each party shall use Proprietary Information disclosed to it by or on behalf of the other party only for the purposes contemplated by this Agreement and shall not disclose such Proprietary Information to any Third Party without the prior written consent of the disclosing party. The foregoing obligations shall survive the expiration or termination of this Agreement for a period of ten (10) years. These obligations shall not apply to Proprietary Information that:

(a) is known by the receiving party at the time of its receipt, and not through a prior disclosure by the disclosing party, as documented by business records;

(b) is at the time of disclosure, or thereafter becomes, published or otherwise part of the public domain without breach of this Agreement by the receiving party;

(c) is subsequently disclosed to the receiving party by a Third Party who has the right to make such disclosure;

(d) is independently developed by the receiving party without the aid, application of Proprietary Information or other information received from the disclosing party and such independent development is properly documented by the receiving party;

(e) is disclosed to governmental or other regulatory agencies (including without limitation Institutional Review Boards) in order to gain approval to conduct clinical trials or to market Product, provided that such disclosure is permitted only to the extent reasonably necessary to obtain such authorizations;

(f) is required to be disclosed by law, regulation, rule, act or order of a governmental authority or agency, provided that the receiving party promptly notifies the other party in order to provide an opportunity to seek a protective order or other similar order with respect to such Proprietary

Information and thereafter discloses only the minimum information required to be disclosed in order to comply, whether or not a protective order or other similar order is obtained by the other party.

Nothing herein shall be interpreted to prohibit Schering from publishing the results of its studies in accordance with industry practices. Each party shall have the right to disclose the other party's Proprietary Information to its Affiliates in connection with the research and development, manufacturing and/or marketing of Product in accordance with the terms of this Agreement, provided that each party shall be responsible for ensuring that its Affiliates comply with the confidentiality and use restrictions set forth herein. The parties acknowledge that the terms and provisions of the Secrecy Agreement dated January 7, 2002, which the parties entered into are incorporated herein by reference.

14.2 No Publicity. A party may not use the name of the other party in any publicity or advertising and may not issue a press release or otherwise publicize or disclose the existence of this Agreement, any information related to this Agreement or the terms or conditions hereof, without the prior written consent of the other party. Nothing in the foregoing, however, shall prohibit a party from making such disclosures as are necessary to comply with applicable federal or state securities laws or any rule or regulation of any nationally recognized securities exchange; provided, however, that the party required to make such disclosure shall use good faith efforts to consult with the other party prior to such disclosure and, where applicable, shall request confidential treatment to the extent available.

ARTICLE XV RECORDS

15.1 Financial and Other Records. Impax shall maintain records with respect to the performance of its obligations under this Agreement, including without limitation its costs incurred in connection therewith. Specifically, but without limitation, Impax shall maintain all records reasonably necessary to support financial accounting entries necessary to support changes in Price pursuant to Section 6.1 hereof. All such records shall be available for inspection, audit and copying by Schering and its representatives and agents, including Schering's auditors, upon reasonable request during normal business hours. All such records shall be maintained until at least two (2) years after the date of a change in Price pursuant to Section 6.1 hereof, or such longer period as may be required by the Laws.

15.2 Product Records. Impax shall maintain all records necessary to comply with the Laws and in accordance with the Health Regulations. In addition, Impax shall prepare and adhere to batch process documentation consistent with the Impax Know-How, and in accordance with its normal procedures, including without limitation quality control records and all raw data relating to each batch processed. Specifically, but without limitation, Impax shall maintain complete and accurate records reasonably necessary to support cGMPs and other

applicable regulatory requirements in the Territory, including without limitation quality control records. All such records shall be available for inspection, and audit by Schering (at its expense) and its representatives and agents, including Schering's auditors upon reasonable request during normal business hours. All such records shall be maintained for the longest period as may be required by the Laws; provided, however, that all records relating to the Manufacture, testing, stability oversight and quality control of each batch of the Product shall be retained at least until the third anniversary of the end of the approved shelf life for all Product from such batch. Impax shall provide Schering on a periodic basis, and at least annually, such information concerning Product, production batches, yields and quality status as is specified in the Health Registrations (commonly referred to as Annual Product Reviews) and as may be reasonably requested by Schering from time to time. Prior to destruction of any record, Impax shall give notice to Schering, which shall have the right to request and retain such record.

15.3 Financial Information Reporting. Impax shall provide Schering on a quarterly basis with quarterly financial statements which are made available to the public and prepared in accordance with GAAP.

ARTICLE XVI MISCELLANEOUS

16.1 Assignment. Neither this Agreement nor any or all of the rights and obligations of a party hereunder shall be assigned, delegated, sold, transferred, sublicensed (except as otherwise provided herein) or otherwise disposed of, by operation of law or otherwise, to any Third Party other than an Affiliate of such party, without the prior written consent of the other party, and any attempted assignment, delegation, sale, transfer, sublicense or other disposition, by operation of law or otherwise, of this Agreement or of any rights or obligations hereunder contrary to this Section 16.1 shall be void and without force or effect; provided, however, Schering may, without such consent, and Impax may with Schering's consent (which consent shall not be unreasonably withheld), assign the Agreement and its rights and obligations hereunder in connection with the transfer or sale of all or substantially all of its assets related to the division or the subject business, or in the event of its merger or consolidation or change in control or similar transaction. This Agreement shall be binding upon, and inure to the benefit of, each party, its Affiliates, and its permitted successors and assigns. Each party shall be responsible for the compliance by its Affiliates with the terms and conditions of this Agreement.

16.2. Force Majeure. Failure of either party hereto to perform its obligations under this Agreement (except the obligation to make payments when due) shall not subject such party to any liability to the other party or place it in breach of any term or condition of this Agreement if such failure is caused by a Force Majeure, provided, however, that the party affected shall promptly notify the other party of the condition constituting a Force Majeure and shall exert Commercially Reasonable Efforts to overcome any such causes and to resume performance of its obligations with all possible speed, and provided, further that nothing contained herein shall require any party to settle on terms

unsatisfactory to such party any strike, lock-out or other labor difficulty, any investigation or proceeding by any public authority, or any litigation by any Third Party. If a condition constituting a Force Majeure exists for more than ninety (90) consecutive days, the parties shall meet to negotiate a mutually satisfactory solution to the problem, if practicable.

16.3. Governing Law. This Agreement shall be governed, interpreted and construed in accordance with the laws of the State of New Jersey, without giving effect to conflict of law principles.

16.4. Waiver. Any delay or failure in enforcing a party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such party's rights to the future enforcement of its rights under this Agreement, nor operate to bar the exercise or enforcement thereof at any time or times thereafter, excepting only as to an express written and signed waiver as to a particular matter for a particular period of time.

16.5. Independent Relationship. Nothing herein contained shall be deemed to create an employment, agency, joint venture or partnership relationship between the parties hereto or any of their agents or employees, or any other legal arrangement that would impose liability upon one party for the act or failure to act of the other party. Neither party shall have any power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other party, or to bind the other party in any respect whatsoever.

16.6. Export Control. This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States of America which may be imposed upon or related to Impax or Schering from time to time by the government of the United States of America. Furthermore, Schering agrees not to export, directly or indirectly, any technical information acquired from Impax under this Agreement or any products using such technical information to any country for which the United States government or any agency thereof at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the Department of Commerce or other agency of the United States government as required by an applicable statute or regulation.

16.7. Entire Agreement; Amendment. This Agreement, including the exhibits and schedules hereto, sets forth the complete and final agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the parties hereto and supersedes and terminates all prior agreements, writings and understandings between the parties with respect to the subject matter hereof. The parties agree that there are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the parties other than as are set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the parties unless reduced to writing and signed by an authorized officer of each party.

16.8. Notices. Each notice required or permitted to be given or sent under this Agreement shall be given by facsimile transmission (with confirmation copy by registered first-class mail) or by registered or overnight courier (return receipt requested), to the parties at the addresses and facsimile numbers indicated below.

If to Impax, to:

Impax Laboratories, Inc.

3735 Castor Avenue
Philadelphia, PA 19124

Attention: Barry R. Edwards, Co-Chief Executive Officer Facsimile No.: 215-289-5932

with copies to:

Sol Genauer, Esq.

Blank, Rome, Comisky & McCauley



If to Schering, to:

Schering Corporation
2000 Galloping Hill Road
Kenilworth, New Jersey 07033

Attention: James Martin, Director of Strategic Sourcing Facsimile No.: (908) 629-3062

with copies to:

Attention: Law Department, Staff Vice-President, Licensing Facsimile No.: (908) 298-2739

Any such notice shall be deemed to have been received on the earlier of the date actually received or the date five (5) days after the same was posted or sent. Either party may change its address or its facsimile number by giving the other party written notice, delivered in accordance with this section.

16.9. Severability. If any provision of this Agreement is declared invalid or unenforceable by a court having competent jurisdiction, it is mutually agreed that this Agreement shall continue in effect except for the part declared invalid or unenforceable by order of such court. The parties shall consult and use diligent efforts to agree upon a valid and enforceable provision which shall be a reasonable substitute for such invalid or unenforceable provision in light of the intent of this Agreement.

16.10. Recording. Each party hereto shall have the right, at any time, to record, register, or otherwise notify this Agreement with or to appropriate governmental or regulatory entities in the Territory, and the other party shall provide reasonable assistance as required in effecting such recording, registration or notification.

16.11. Counterparts. This Agreement shall become binding when any one or more counterparts hereof, individually or taken together, have been executed on behalf of each of the parties hereto. This Agreement may be executed in any number of counterparts, each of which shall be an original as against any party whose signature appears thereon, but all of which taken together shall constitute but one and the same instrument.

16.12 Arbitration. Prior to submission of any controversy or dispute arising out of or relating to this Agreement ("Dispute") to arbitration in accordance with this Section 16.12, the Parties will negotiate in good faith to resolve such Dispute. If the Parties cannot reach agreement within ten (10) days of written notice by a Party to the other that a Dispute exists, the Dispute shall be settled by arbitration before three (3) neutral arbitrators (at least one of which arbitrators shall have substantial intellectual property experience) in accordance with the then current rules of the American Arbitration Association. Any such arbitration shall be conducted and determined in Philadelphia, Pennsylvania. The decision of the arbitrators shall be binding on the parties. The award rendered by the arbitrators shall be final and judgment may be entered upon it in any court having jurisdiction thereof. The prevailing party shall be entitled as part of the award to all reasonable fees and expenses incurred in connection with the arbitration, including the reasonable fees and expenses of the arbitrators and reasonable attorney's fees. The parties agree that arbitration proceedings must be instituted within one (1) year after knowledge of the occurrence of the breach and that the failure to institute arbitration proceedings within such period shall constitute a waiver of all claims and an absolute bar to institution of any and all proceedings to arbitrate or adjudicate such claims.

IN WITNESS WHEREOF, Schering and Impax have caused this Agreement to be executed by their duly authorized officers as of the day and year first above written.

SCHERING CORPORATION

IMPAX LABORATORIES, INC.

By: /s/ Steven Chellevoid

By: /s/ Barry R. Edwards

Name: Steven Chellevoid
Title: Senior Vice President -
Technical Operations

Name: Barry R. Edwards
Title: Co-Chief Executive Officer

Date: June 10, 2002 Date: June 18, 2002

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