IMPAX LABORATORIES INC

FORM 8-K
(Current report filing)

Filed 08/04/14 for the Period Ending 08/04/14

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

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 4, 2014

Impax Laboratories , Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-34263**	**65-0403311**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

30831 Huntwood Avenue, Hayward, CA	**94544**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(510) 240-6000**

Not Applicable

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

On August 4, 2014, Impax Laboratories, Inc. (the "Company") issued a press release announcing its receipt of a Form 483 from the U.S. Food and Drug Administration (the "FDA") related to the FDA's inspection of the Company's Hayward, California manufacturing facility. A copy of the press release is attached hereto as Exhibit 99.1 and a redacted copy of the Form 483 issued by the FDA is attached hereto as Exhibit 99.2, each of which is incorporated by reference herein.

"Safe Harbor" statement under the Private Securities Litigation Reform Act of 1995:

To the extent any statements made in this Current Report on Form 8-K contain information that is not historical, these statements are forward-looking in nature and express the beliefs and expectations of management. Such statements are based on current expectations and involve a number of known and unknown risks and uncertainties that could cause actual developments and results to differ significantly from those that are expressed or implied by such forward-looking statements. Such risks and uncertainties include, but are not limited to: fluctuations in revenues and operating income; the Company's ability to promptly correct the issues raised in the warning letter and Form 483 observations received from the FDA; the Company's ability to successfully develop and commercialize pharmaceutical products in a timely manner; the impact of competition; the substantial portion of our total revenues derived from sales of a limited number of products; the Company's ability to sustain profitability and positive cash flows; any delays or unanticipated expenses in connection with the operation of the Company's manufacturing facilities; product development risks and the difficulty of predicting FDA filings and approvals; the impact of market perceptions of the Company and the safety and quality of the Company's products; the Company's ability to comply with legal and regulatory requirements governing the healthcare industry; the regulatory environment; the Company's ability to manage growth, including through potential acquisitions; and other risks described in the Company's periodic reports filed with the Securities and Exchange Commission . Forward-looking statements speak only as to the date on which they are made, and the Company undertakes no obligation to update publicly or revise any forward-looking statement, regardless of whether new information becomes available, future developments occur or otherwise, except to the extent required by applicable law.

Item 9.01 Fi nancial Statements and Exhibits .

(d) Exhibits.

The following exhibits are filed herewith.

Exhibit No.	Description
99.1	Press release issued August 4, 2014
99.2	FDA Form 483

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 hereunto duly authorized.

Dated: August 4, 2014

IMPAX LABORATORIES, INC .

By: /s/ Bryan M. Reasons
Name: Bryan M. Reasons
Title: Senior Vice President, Finance, and Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release issued August 4, 2014
99.2	FDA Form 483

Exhibit 99.1

FDA Performs Inspection of Impax ’s Hayward Facility

HAYWARD, Calif., August 4 , 2014 – Impax Laboratories, Inc. (NASDAQ: IPXL) today announced that the U.S. Food and Drug Administration (FDA) performed a re-inspection of the Company’s Hayward, California manufacturing facility from June 16 to July 31, 2014. At the conclusion of the inspection, the FDA issued a Form 483 with seven inspectional observations., two of which are designated as repeat observations.

The FDA did not provide any status or classification to these observations and, pursuant to its established regulatory process, will defer classification until it has reviewed the Company’s response to the inspection. The Company is working diligently to address FDA’s observations and will respond to them within 15 days of receipt of the Form 483.

“Addressing these latest observations and advancing our quality improvement initiatives are our top priorities,” said Fred Wilkinson, president and chief executive officer of Impax Laboratories. “Our dedicated teams are focused on creating a world class quality organization.”

“While the past week has been challenging, I remain enthusiastic about Impax’s future and the opportunities ahead of us. We have a track record of development and commercialization success, and a strong pipeline of pending products. In addition, we have the financial resources and balance sheet to create new revenue sources through internal and external development, while pursuing strategic and accretive M&A opportunities.”

The Company has provided a redacted version of the Form 483 as an exhibit in a Current Report on Form 8-K filed with the SEC concurrently with the issuance of this press release .

About Impax Laboratories, Inc.

Impax Laboratories, Inc. (Impax) is a technology based specialty pharmaceutical company applying its formulation expertise and drug delivery technology to the development of controlled-release and specialty generics in addition to the development of central nervous system disorder branded products. Impax markets its generic products through its Global Pharmaceuticals division and markets its branded products through the Impax Pharmaceuticals division. Additionally, where strategically appropriate, Impax develops marketing partnerships to fully leverage its technology platform and pursues partnership opportunities that offer alternative dosage form technologies, such as injectables, nasal sprays, inhalers, patches, creams and ointments. For more information, please visit the Company's Web site at: www.impaxlabs.com.

" *Safe Harbor" statement under the Private Securities Litigation Reform Act of 1995:*

To the extent any statements made in this news release contain information that is not historical; these statements are forward-looking in nature and express the beliefs and expectations of management. Such statements are based on current expectations and involve a number of known and unknown risks and uncertainties that could cause the Company's future results, performance, or achievements to differ significantly from the results, performance, or achievements expressed or implied by such forward-looking statements. Such risks and uncertainties include, but are not limited to: fluctuations in revenues and operating income; the Company's ability to promptly correct the issues raised in the warning letter and Form 483 observations received from the FDA; the Company's ability to successfully develop and commercialize pharmaceutical products in a timely manner; reductions or loss of business with any significant customer; the impact of consolidation of the Company's customer base; the impact of competition; the substantial portion of our total revenues derived from sales of a limited number of products; the Company's ability to sustain profitability and positive cash flows; any delays or unanticipated expenses in connection with the operation of the Company's manufacturing facilities; the effect of foreign economic, political, legal, and other risks on the Company's operations abroad; the uncertainty of patent litigation and other legal proceedings; the increased government scrutiny on the Company's agreements with brand pharmaceutical companies; product development risks and the difficulty of predicting FDA filings and approvals; consumer acceptance and demand for new pharmaceutical products; the impact of market perceptions of the Company and the safety and quality of the Company's products; the Company's determinations to discontinue the manufacture and distribution of certain products; the Company's ability to achieve returns on its investments in research and development activities; the Company's inexperience in conducting clinical trials and submitting new drug applications; the Company's ability to successfully conduct clinical trials; the Company's reliance on third parties to conduct clinical trials and testing; the Company's lack of a license partner for commercialization of IPX066 outside of the United States; impact of illegal distribution and sale by third parties of counterfeits or stolen products; the availability of raw materials and impact of interruptions in the Company's supply chain; the Company's policies regarding returns, allowances and chargebacks; the use of controlled substances in the Company's products; the effect of current economic conditions on our industry, business, results of operations and financial condition; disruptions or failures in the Company's information technology systems and network infrastructure; the Company's reliance on alliance and collaboration agreements; the Company's reliance on licenses to proprietary technologies; the Company's dependence on certain employees; the Company's ability to comply with legal and regulatory requirements governing the healthcare industry; the regulatory environment; the Company's ability to protect its intellectual property; exposure to product liability claims; risks relating to goodwill and intangibles; changes in tax regulations; the Company's ability to manage growth, including through potential acquisitions; the restrictions imposed by the Company's credit facility; uncertainties involved in the preparation of the Company's financial statements; the Company's ability to maintain an effective system of internal control over financial reporting; the effect of terrorist attacks on the Company's business; the location of the Company's manufacturing and research and development facilities near earthquake fault lines; expansion of social media platforms; and other risks described in the Company's periodic reports filed with the Securities and Exchange Commission. Forward-looking statements speak only as to the date on which they are made, and the Company undertakes no obligation to update publicly or revise any forward-looking statement, regardless of whether new information becomes available, future developments occur or otherwise.

Company Contact:
Mark Donohue
Investor Relations and Corporate Communications
(215) 558-4526
www.impaxlabs.com

Exhibit 99.2

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 Phone: 510-337-6700 Fax: 510-337-6702 Industry Information: www.fda.gov/oc/industry	06/16/2014-07/31/2014* FEI NUMBER 3004182921

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: George Frederick Wilkinson, President and Chief Executive Officer

FIRM NAME	STREET ADDRESS
Impax Laboratories, Inc.	31145 San Antonio Street
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Hayward, CA 94544-7905	Drug Manufacturer

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically,

A.) On 07/09/2014, we reviewed Laboratory Investigation Report (LIR) PR218999, created on 10/11/2012, and observed that release testing for Pyridostigmine Bromide Tablets, 60mg (ANDA [redacted] bulk lot [redacted] had a reported assay value of [redacted] on 10/11/2012. The Quality Control Action Limit (QCAL) for the Pyridostigmine Bromide Tablets, 60mg assay is [redacted] as stated in written procedure 2QCC-001.02 titled, "Evaluation of Out-of-Specification (OOS), Quality Control Alert Limit (QCAL) and Aberrant Laboratory Results" Effective Date August 24, 2012. Confirmation testing was performed during the laboratory investigation (PR218999) on 10/11/2012 and the resulting assay values were out of specification, approximately [redacted] (specification range: [redacted] The firm concluded in PR218999 in part, "…there was no lab error found, the original below QCAL AS results for the Affected lot were true results…."

The investigation did not address the ramifications of generating out-of-specification confirmatory test results, nor did the investigation expand into manufacturing operations. Lot [redacted] has an expiration date of August 2015 and was approved by Quality Assurance and released to market on 11/13/2012.

B.) On 07/24/2014, we reviewed Laboratory Investigation Report (LIR) PR399755, created on 09/26/2013, for the release testing of Fludrocortisone Acetate Tablets, 0.1mg (ANDA [redacted], bulk lot [redacted]. We observed the result from one of the [redacted] (AS1) had a value of [redacted] performed on 09/17/2013, which is below the QCAL of [redacted] per written procedure 2QCC-001.02 titled, "Evaluation of Out-of-Specification (OOS), Quality Control Alert Limit (QCAL) and Aberrant Laboratory Results" Effective Date August 24, 2013. During the

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Lance M. De Souza, Investigator Eric L. Dong, Chemist Stephanie A. Slater, Investigator	7/31/2014

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 Phone: 510-337-6700 Fax: 510-337-6702 Industry Information: www.fda.gov/oc/industry	06/16/2014-07/31/2014*
	FEI NUMBER 3004182921

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: George Frederick Wilkinson, President and Chief Executive Officer

FIRM NAME	STREET ADDRESS
Impax Laboratories, Inc.	31145 San Antonio Street
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Hayward, CA 94544-7905	Drug Manufacturer

laboratory investigation (PR399755), the firm used standard and sample solutions that were [redacted] past expiry to perform confirmatory tests on 09/27/2013. The confirmatory re-vialed result was [redacted] for AS1, which was out of specification [redacted] The firm concluded in PR399755: "Since the results were consistent between the affected samples and the control samples, the original results were considered confirmed."

Based on test method 2TFDCAS.01 titled, "Fludrocortisone Acetate Tablets, USP Identification, Assay, Uniformity and Stability Test Method", the firm claimed that Fludrocortisone Acetate degrades [redacted] However, this investigation did not consider the [redacted] of the product as described in Report No.: SUM-AR-13-0057 Rev. 01, titled "Forced Degradation Studies for Fludrocortisone Acetate Tablets, USP Identification, Assay, Uniformity and Stability Test Method" dated 07/23/2013. Furthermore, the investigation and written procedure 2QCC-001.02 did not justify the use of these expired testing solutions.

OBSERVATION 2

The accuracy, sensitivity, specificity, and reproducibility of test methods have not been established and documented.

Specifically,

A.) On 07/07/2014, we reviewed method validation report VTMSAS.03 titled, "Tamsulosin HCl Capsules Identification, Assay Uniformity, and Stability Test Method Validation" dated 01/14/2008. We observed that the [redacted] changed multiple conditions simultaneously. No justification was provided for this approach that may mask the opposing effects of multiple changes. Additionally, your written procedure 2LAB-054.00 titled, "Validation and Verification for Phase III and Commercial Test Methods", Effective Date 03/19/2014, does not specify to perform each [redacted] condition one at a time.

B.) On 07/14/2014, we reviewed the executed Method Transfer Protocol #MT-051 titled, "Tamsulosin HCl Capsules, 0.4mg" dated 12/01/2008. The absolute difference of the average results from each laboratory was [redacted] This significant deviation was not addressed by your firm and there was no documented justification for the continued use of the assay method 2TTMSAS titled, "Tamsulosin HCL Capsules Identification, Assay, Uniformity And Stability Test Method", Effective 06/15/2009.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	LMD ELD SAS	Lance M. De Souza, Investigator Eric L. Dong, Chemist Stephanie A. Slater, Investigator	7/31/2014

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 Phone: 510-337-6700 Fax: 510-337-6702 Industry Information: www.fda.gov/oc/industry	06/16/2014-07/31/2014* FEI NUMBER 3004182921

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: George Frederick Wilkinson, President and Chief Executive Officer

FIRM NAME	STREET ADDRESS
Impax Laboratories, Inc.	31145 San Antonio Street
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Hayward, CA 94544-7905	Drug Manufacturer

C.) A demonstration of equivalency has not been performed for all in-house test methods where an applicable USP test method is also available. For example, Document No. VP2TPYBAS.00 titled, "Supplemental Method Validation Report for The Assay Test Method (2TPYBAS) for Pyridostigmine Bromide Tablets, USP, 60mg", dated 06/27/2013 was based on USP, but was significantly modified and lacked a documented USP equivalency assessment. Additionally, other products, which lack an equivalency assessment includes: Bupropion HCl ER Tablets, 100mg, 150mg, and 200mg; Bupropion HCl ER (XL) Tablets, 150mg; Dantrolene Sodium Capsules, 25mg, 50mg, and 100mg; Dipyridamole Tablets 25mg, 50mg, and 75mg; Orphenadrine Citrate ER Tablets, 100mg; Oxybutynin Chloride ER Tablets 5mg, 10mg, and 15mg; and Rimantadine Hydrochloride Tablets, 100mg.

THIS IS A REPEAT OBSERVATION.

OBSERVATION 3

Written procedures for cleaning and maintenance fail to include description in sufficient detail of methods, equipment and materials used and instructions for protection of clean equipment from contamination prior to use.

Specifically,

A.) On 07/22/2014, we observed Quality Assurance (QA) Inspectors perform cleaning verification procedures on your [redacted] (equipment number IP5025) and [redacted] (equipment number EQ6346). After the sampling of Fludrocortisone Acetate API residue and cleaning agent residue was completed, we observed residual rayon fibers on the inner surface of the [redacted] The trace rayon fiber strands measured up to 1.2 cm in length. Your written procedure 2QUA-085.03 titled, "Equipment Swab, Rinse Preparation and Sampling" Effective Date 07/21/2014 does not instruct employees to perform a visual inspection check of the swab locations after swabbing, nor does it instruct the cleaning of the swab areas post-sampling.

B.) Written procedure 2QUA-085.03 titled, "Equipment Swab, Rinse Preparation and Sampling" Effective Date 07/21/2014 was not consistent with other cleaning validation test methods that are currently used by QA Inspectors. For example, on 07/22/2014, your QA Inspectors followed 2QUA-085.03 and test method 2TFDCCV.03 titled, "Fludrocortisone Acetate Tablets Cleaning Validation Test Method" Effective Date

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	LMD EMD SAS	Lance M. De Souza, Investigator Eric L. Dong, Chemist Stephanie A. Slater, Investigator	7/31/2014

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 Phone: 510-337-6700 Fax: 510-337-6702 Industry Information: www.fda.gov/oc/industry	06/16/2014-07/31/2014* FEI NUMBER 3004182921

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: George Frederick Wilkinson, President and Chief Executive Officer

FIRM NAME	STREET ADDRESS
Impax Laboratories, Inc.	31145 San Antonio Street
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Hayward, CA 94544-7905	Drug Manufacturer

11/20/2003. Written procedure 2QUA-085.03, section 5.5.3 states in part, "Document the start time of the soaking [of rayon for sampling swabs] in SOP VAL-029 attachments" and section 5.5.5 states in part, "Document the End Time for soaking [of rayon for sampling swabs] in SOP 2VAL-029 attachments." However, according to cleaning validation test method 2TFDCCV.03, the sample preparation steps do not require documentation of the soak start and stop times.

OBSERVATION 4

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically,

The [redacted] spectrophotometer located in the GMP Analytical R&D Laboratory (equipment number IP8032, located in Building B8) and the [redacted] spectrophotometer in the QC Laboratory (equipment number IP4263 in Building B5) did not have validated data integrity acquisition systems to ensure that analysts cannot re-write or delete analytical data during analyses. Both systems were used in GMP activities, such as release testing, raw material testing, stability testing, method validation, and cleaning verification.
THIS IS A REPEAT OBSERVATION.

OBSERVATION 5

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically,

A.) On 6/16/2014, we found a plastic bag containing thirteen (13) auto sampler vials next to an Instrument Ion Chromatography System (equipment number IC3). The plastic bag was labeled, "HPLC 236 B", which references a different type of laboratory instrument, HPLC (high performance liquid chromatography).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	LMD EDD SAS	Lance M. De Souza, Investigator Eric L. Dong, Chemist Stephanie A. Slater, Investigator	7/31/2014

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 Phone: 510-337-6700 Fax: 510-337-6702 Industry Information: www.fda.gov/oc/industry	06/16/2014-07/31/2014* FEI NUMBER 3004182921

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: George Frederick Wilkinson, President and Chief Executive Officer

FIRM NAME	STREET ADDRESS
Impax Laboratories, Inc.	31145 San Antonio Street
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Hayward, CA 94544-7905	Drug Manufacturer

Six of the thirteen vials lacked reference to the test method or notebook. A single vial labeled, "H2O" was not labeled consistent with instructions given by written procedure 2LAB-010.00 titled, "Control of Labeling of Chemicals, Reagents, and Solutions" Effective Date 03/04/2014, in that it was missing references to the test method, notebook, and date prepared. Written procedure 2LAB-010.00 section 5.3 Standard and Sample Solution Labeling, states in part, "Label standard solution with the name of the standard, date of preparation, analyst initials, method and reference…Label sample solution with the sample name, date of preparation, analyst initials, method and reference."

B.) On 07/28/2014, we reviewed laboratory notebook number WI24900, pages 22 to 27, which described the stability testing for dissolution of Fludrocortisone Acetate Tablets, 0.1mg lot number 10000283 [redacted] weeks, [redacted]. We found that the standard accuracy check was outside of the acceptable range [redacted] with a value of [redacted]. The analyst did not follow written procedure 2QCC-008.03 titled, "General Chromatography" Effective Date 04/28/2014, section 5.4.6.1, which instruets analysts to "Re-inject the standard check solution to make sure the failure was not due to equipment malfunction." The analyst proceeded to step 5.4.6.3, and prepared another set of two standard solutions and repeated the standard check.

C.) On 06/17/2014, we observed two small, unlabeled plastic bags containing tablets in the large waste bin in Building B2 Room 196. One bag contained 11 orange tablets. The second bag contained 12 purple tablets. The bags did not have the required waste label affixed to them and they were not entered in the waste bin logbook per written procedure 2MFG-149.01 titled, "Solid Non-Controlled Substance Waste Disposal" Effective Date 06/05/2014.

OBSERVATION 6

Buildings used in the manufacturing and holding of a drug product are not maintained in a good state of repair.

Specifically,

On 06/16/2014, during our inspection of the walk-in Stability Chamber (equipment number IP5166, 23-27oC, 55-65% RH) we observed the following:

	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
SEE REVERSE OF THIS PAGE	LMD EDD SAS	Lance M. De Souza, Investigator Eric L. Dong, Chemist Stephanie A. Slater, Investigator	7/31/2014

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 Phone: 510-337-6700 Fax: 510-337-6702 Industry Information: www.fda.gov/oc/industry	06/16/2014-07/31/2014*
	FEI NUMBER 3004182921

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: George Frederick Wilkinson, President and Chief Executive Officer

FIRM NAME	STREET ADDRESS
Impax Laboratories, Inc.	31145 San Antonio Street
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Hayward, CA 94544-7905	Drug Manufacturer

1.) Rust stains were on the metallic floor of the Stability Chamber underneath rubber floor mats.
2.) The copper piping elbow was covered in silicone-epoxy.
3.) One ceiling tile was sagging.
4.) Corrosion was on the condensate drain pan.

This walk-in Stability Chamber is used for the storage of GMP commercial products on stability studies, products for R&D Submission studies, and products on clinical stability studies.

OBSERVATION 7

Changes to written procedures are not drafted, reviewed and approved by the appropriate organizational unit.

Specifically,

A.) Change Control No. 200005111 dated 04/30/2014 requested a change to written procedure 2QUA-092.03 titled, "Sampling Plans for Process Performance Qualification Lots" to remove references to "FDA Guidance for Industry, Powder Blends and Finished Dosage Units Stratified In Process Dosage Unit Sampling and Assessment, Draft October and November 2003" from the procedure. However, the most recent version of the procedure, 2QUA-092.04, section 6.1.2.1, was not changed according to this change control request.

B.) Written procedure 2QCC-016.04 titled, "Data Review Procedure for Quality Control Laboratory" Effective Date 05/12/2014 section 5.3.1.1 refers to "Attachment 1". Attachment 1 is a guideline that can be used by Quality Reviewers to review laboratory data. We observed that Attachment 1 was missing from 2QCC-016.04. According to section 5.3.1.1, "The reviewer is responsible for reviewing the material in both the guideline and topics covered in this SOP". Furthermore, on 7/15/2014, we observed QC Notebook Reviewer A.G.P. use an uncontrolled, Excel spreadsheet during a laboratory notebook review.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
		Lance M. De Souza, Investigator Eric L. Dong, Chemist Stephanie A. Slater, Investigator	7/31/2014