

BRISTOL MYERS SQUIBB CO

FORM 8-K (Current report filing)

Filed 04/19/00 for the Period Ending 04/19/00

Address	345 PARK AVE NEW YORK, NY 10154
Telephone	2125464000
CIK	0000014272
Symbol	BMY
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

BRISTOL MYERS SQUIBB CO

FORM 8-K (Unscheduled Material Events)

Filed 4/19/2000 For Period Ending 4/19/2000

Address	345 PARK AVE NEW YORK, New York 10154
Telephone	212-546-4000
CIK	0000014272
Industry	Major Drugs
Sector	Healthcare
Fiscal Year	12/31

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

April 19, 2000
Date of Report (Date of earliest event reported)

BRISTOL-MYERS SQUIBB COMPANY

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

1-1136
(Commission File Number)

22-079-0350
(IRS Employer Identification No.)

345 Park Avenue, New York
(Address of principal executive offices)

10154
(Zip Code)

(212) 546-4000
(Registrant's telephone number, including area code)

Item 5. Other Events.

Attached hereto and incorporated herein by reference as Exhibit 99.1 is a copy of a press release issued by Bristol-Myers Squibb Company on April 19, 2000.

Item 7. Financial Statements and Exhibits.

(c) Exhibits

(99.1) Press Release, dated April 19, 2000.

SIGNATURE

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.

BRISTOL-MYERS SQUIBB COMPANY

By: /s/ Sandra Leung

Name: Sandra Leung
Title: Secretary

Dated: April 19, 2000

EXHIBIT INDEX

(99.1) Press Release, dated April 19, 2000.

(PRINCETON, N.J., April 19, 2000)--Bristol-Myers Squibb Company (NYSE:BMJ) is voluntarily withdrawing its current New Drug Application (NDA) for VANLEV™ (omapatrilat) from the U.S. Food and Drug Administration (FDA). The company now expects to resubmit its application early next year. Bristol-Myers Squibb is taking this action in response to questions raised recently by the agency regarding the comparative incidence and severity of an infrequent side effect known as angioedema reported within the NDA database. Angioedema is a localized swelling that generally affects the face, throat, lips or tongue that can be triggered by food and commonly used drugs such as ACE-inhibitors, nonsteroidal anti-inflammatory agents and some antibiotics.

The company is cooperating with the FDA to identify the additional data needed to resolve the agency's questions. Simultaneously, prospective controlled clinical studies in patients with hypertension and heart failure will continue. Regulatory filing activities outside the U.S. for VANLEV are proceeding as planned.

VANLEV is the most clinically developed member of the vasopeptidase inhibitor class of cardiovascular compounds. VANLEV was designed to simultaneously inhibit two key enzymes--angiotensin-converting enzyme (ACE) and neutral endopeptidase (NEP)--which regulate blood pressure. Clinical studies have demonstrated that VANLEV significantly reduces both systolic (top number) and diastolic (bottom number) blood pressure.

In January 2000, the FDA provided a priority review for VANLEV, a status the agency grants for drugs considered to be a significant therapeutic advance under the Prescription Drug User Fee Act (PDUFA). VANLEV became the first antihypertensive to receive a priority review under this system.

Hypertension, or high blood pressure, affects more than 600 million people worldwide. Three of four people with high blood pressure in the U.S. are not at or below the recommended target goal of lower than 140/90 mmHg and remain at higher risk for heart attack, stroke, heart failure, and kidney disease. Bristol-Myers Squibb is committed to improving the lives of people with high blood pressure and believes VANLEV will be a significant advance in extending and enhancing human life.

End of Filing

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