FOREST LABORATORIES INC
Form 8-K
July 02, 2002

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) July 2, 2002

FOREST LABORATORIES, INC.

(Exact name of registrant as specified in its charter)

Delaware

1-5438	11-1798614
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

909 Third Avenue, New York, New York

10022
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: 212-421-7850

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

Item 5. Other Events

Exhibit 99(1) to this Report is a Press Release issued by Forest Laboratories, Inc. on July 2, 2002. The Press Release reports the receipt by Lipha S.A., a French subsidiary of Merck KGaA of Germany, of notification from the United States Food and Drug Administration that the New Drug Application submitted by Lipha for acamprosate, a medication designed to help maintain abstinence in patients with alcohol dependence, is not approvable at this time. Forest licenses the United States marketing and distribution rights to acamprosate from Lipha.

Item 7. Financial Statements, Pro Forma Financial Information and Exhibits

(c) Exhibit 99(1). Press Release of Forest Laboratories, Inc. dated July 2, 2002.

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.

FOREST LABORATORIES, INC.

By: /s/Howard Solomon

Howard Solomon,

Chairman of the Board

Date: July 2, 2002

EXHIBIT 99(1)

Contact:

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FDA ISSUES NON-APPROVABLE LETTER FOR ACAMPROSATE

NEW YORK, July 2, 2002 - The U.S. Food and Drug Administration (FDA) has determined that the New Drug Application (NDA) submitted by Lipha S.A. for acamprosate, a medication designed to help maintain abstinence in patients with alcohol dependence, is not approvable at this time. Lipha S.A., a French subsidiary of Merck KGaA based in Darmstadt, Germany, developed acamprosate and licensed the U.S. marketing and distribution rights to Forest Laboratories in October 2001. Lipha's NDA for acamprosate was filed in December 2001, and received a priority review designation from the FDA.

Despite the conclusion from its advisory committee on May 10, 2002 that clinical trial data for acamprosate submitted in the NDA demonstrated efficacy, the FDA, upon completing its review of the application, has indicated that the data submitted did not adequately establish the safety and efficacy of acamprosate. The FDA has requested that at least one additional U.S. clinical trial evaluating safety and efficacy be conducted as well as additional pharmacokinetic analyses and additional pre-clinical studies.

Lipha conducted several multi-center, placebo-controlled clinical trials that tested the safety and efficacy of acamprosate in more than 4,500 patients with alcohol dependence. In the trials, acamprosate was shown to consistently increase abstinence rates when used as part of a multidisciplinary approach that included psychosocial or behavioral therapies. The studies also demonstrated that side effects for acamprosate were generally mild, with the most frequently reported side effect being diarrhea**.** Acamprosate is currently approved and available in 24 countries outside the United States and was most recently approved in the United Kingdom in 1995 and in Australia 1999 and Italy in 1999.

Except for the historical information contained herein, this release contains forward looking statements that involve a number of risks and uncertainties, including the difficulty of predicting FDA approvals, acceptance and demand for new pharmaceutical products, the impact of competitive products and pricing, the timely development and launch of new products and the risk factors listed from time to time in the Company's SEC reports, including the Company's Annual Report on Form 10-K for the fiscal year ended March 31, 2002, along with any Merck KGaA reports.

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