

NOVEN PHARMACEUTICALS INC

Form 8-K

April 29, 2003

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**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): April 25, 2003

**Noven Pharmaceuticals, Inc.**

11960 S.W. 144th Street, Miami, Florida 33186

305-253-5099

Incorporated under the laws of the  
State of Delaware

Commission File Number  
0-17254

I.R.S. Employer Identification Number  
59-2767632

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EX-99.1 PRESS RELEASE

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**Item 5. Other Events.**

On April 25, 2003, Noven Pharmaceuticals, Inc. received notification from the U.S. Food and Drug Administration (FDA) that the New Drug Application (NDA) for its methylphenidate transdermal system is not approvable. A not approvable letter is issued if the FDA believes that the application contains insufficient information for an approval action at the time of issuance. The product is licensed to Shire Pharmaceuticals Group plc.

A copy of Noven's press release announcing the FDA action is filed as Exhibit 99.1 and incorporated herein by this reference.

**Item 7. Exhibits**

(c) Exhibits.

99.1 Press release dated April 28, 2003 announcing the receipt of a not approvable letter from the FDA.

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**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.

NOVEN PHARMACEUTICALS, INC.

/s/ Jeffrey F. Eisenberg

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Jeffrey F. Eisenberg  
Vice President, General Counsel and  
Corporate Secretary

Date: April 29, 2003

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| <b><u>Exhibit No.</u></b> | <b><u>Description</u></b>   |
|---------------------------|---|
| 99.1                      | Press Release, dated April 28, 2003, announcing the receipt of a not approvable letter from the FDA |