

Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 8-K

ENDO PHARMACEUTICALS HOLDINGS INC
Form 8-K
November 27, 2001

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): November 27, 2001
(November 26, 2001)

ENDO PHARMACEUTICALS HOLDINGS INC.

(Exact name of registrant as specified in its charter)

DELAWARE	39040	13-4022871
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

100 Painters Drive Chadds Ford, Pennsylvania	19317
(Address of principal executive offices)	(Zip Code)

(610) 558-9800

(Registrant's telephone number, including area code)

N/A

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

Item 7. Financial Statements and Exhibits.

(a) Financial Statements of Business Acquired.

Not applicable.

(b) Pro Forma Financial Information.

Not applicable.

(c) Exhibits.

Exhibit Number	Description
99.1	Press release issued by Endo Pharmaceuticals Holdings Inc.

Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 8-K

on November 26, 2001

Item 9. Regulation FD Disclosure.

On November 26, 2001, the Registrant issued a press release, a copy of which is filed herewith as Exhibit 99.1 and is incorporated herein by reference.

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.

ENDO PHARMACEUTICALS HOLDINGS INC.
(Registrant)

By: /s/ CAROL A. AMMON

Name: Carol A. Ammon
Title: President & Chief Executive
Officer

Dated: November 27, 2001

INDEX TO EXHIBITS

Exhibit No.	Description
99.1	Press release issued by Endo Pharmaceuticals Holdings Inc. on November 26, 2001

Exhibit 99.1

FOR IMMEDIATE RELEASE

CONTACT:
Robert Siegfried/Jeremy Fielding
Kekst and Company
212-521-4800

Endo Receives FDA Approval for New Percocet (R) Strengths

Reduced Acetaminophen Should Ease Concern About Daily Acetaminophen Limits

Chadds Ford, Pa., November 26, 2001 -- Endo Pharmaceuticals

Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 8-K

Holdings Inc. (Nasdaq: ENDP; ENDPW) today announced the Food and Drug Administration's approval of the abbreviated new drug application to market Percocet(R) 7.5/325 and 10/325 oxycodone/acetaminophen tablets that was filed by Endo Pharmaceuticals Inc., a wholly owned subsidiary of Endo Pharmaceuticals Holdings. Percocet(R), the leading brand of oxycodone/acetaminophen on the market, is indicated for the treatment of moderate to moderately severe pain. The new reformulated Percocet(R) 7.5/325 and 10/325 strengths offer proven pain relief with reduced acetaminophen content as compared with previously available formulations of the pain-relieving drug.

Carol A. Ammon, president and CEO of Endo Pharmaceuticals stated, "The new reformulated Percocet(R) 7.5/325 and 10/325 underscore the strengths of Endo in the marketplace. We believe that we have a robust pipeline that feeds into our growing marketing and sales organization, and the gold standard in pain management with our Percocet(R) products.

"These new formulations were developed in response to physician demand. These formulations combine the higher strengths of 7.5 and 10 milligrams of oxycodone that physicians have increasingly adopted, with up to 50% less acetaminophen per day than previous formulations. This reinforces Endo's commitment to providing a broad range of safe and effective pain management products," Ms. Ammon said.

"With this new formulation, physicians can still take advantage of the synergistic action of the two analgesics combined, but without worrying about exceeding the daily limit of acetaminophen," said Nathaniel Katz, MD, Assistant Professor of Anesthesia at Harvard Medical School. "This will really be helpful to patients who may need higher doses of oxycodone to relieve their pain."

The new reformulated strengths, which are expected to be available in pharmacies within the next week to ten days, will potentially enable patients to take their Percocet(R) on a simpler dosing schedule, allowing them to take fewer tablets per day, and less frequently than the original 5mg tablet. And due to the lower acetaminophen levels, these new strengths may allow physicians to prescribe Percocet(R) 7.5/325 and 10/325 for more long-term use than previously acceptable.

"The new strengths continue to deliver the dual benefits of oxycodone and acetaminophen, while lowering the risk of excessive acetaminophen exposure," said Lori Reisner, Pharm.D. and Associate Clinical Professor of Pharmacy at the University of California in San Francisco. "The ever-increasing number of acetaminophen-containing products and other over-the-counter pain relievers requires pharmacists to be diligent in reminding physicians and patients about the appropriate level of usage."

The most frequently reported side effects of Percocet(R) include lightheadedness, dizziness, sedation, nausea and vomiting. Oxycodone can produce drug dependence and has the potential for being abused. Physicians are reminded that the total daily dose of acetaminophen must be carefully considered in the use of any combination product. For complete prescribing information call 800/462-3636.

Endo Pharmaceuticals Holdings Inc.

Endo Pharmaceuticals is a fully integrated specialty pharmaceutical company with market leadership in pain management products. The company researches, develops, produces and markets a broad product offering of both branded and generic pharmaceuticals, meeting the needs of healthcare professionals and consumers alike. This and past press releases of Endo Pharmaceuticals Holdings Inc. are available at Endo's Web site at

Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 8-K

<http://www.endo.com>.

To the extent any statements made in this release contain information that is not historical, these statements are essentially forward-looking and are subject to risks and uncertainties. As a result of such risks and uncertainties, which include, but are not limited to, the difficulty of predicting FDA approvals, risks with respect to technology and product development, the effect of competing products and prices, uncertainties regarding intellectual property protection, uncertainties as to the outcome of litigation, changes in operating results and other risks discussed from time to time in Endo's filings with the Securities and Exchange Commission, actual results may differ materially from those expressed or implied by such forward-looking statements.

#