

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 3, 2001

ENZON, INC.

(Exact name of registrant as specified in its charter)

|   |                             |                                  |
|---|-----------------------------|----------------------------------|
| Delaware  | 0-12957                     | 22-2372868                       |
| (State or other jurisdiction of<br>incorporation) | (Commission<br>File Number) | (IRS Employer<br>Identification) |

20 Kingsbridge Road, Piscataway, New Jersey 08854  
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (732) 980-4500

NA

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

Item 5. Other Events

Enzon, Inc. reported that Schering-Plough Corporation has advised it that Schering-Plough has submitted a supplemental Biologics License Application (sBLA) to the U.S. Food and Drug Administration (FDA) seeking marketing approval for PEG-INTRON(TM) (peginterferon alfa-2b) Redipen(TM) Single-dose Delivery System. PEG-INTRON (peginterferon alfa-2b) is a longer-acting form of INTRON(R) A (interferon alfa-2b, recombinant) Injection that uses proprietary PEG technology developed by Enzon. Under the Company's licensing agreement with Schering-Plough, Enzon is entitled to royalties on worldwide sales of PEG-INTRON.

Schering-Plough has reported that PEG-INTRON Redipen Single-dose Delivery System consists of a dual-chamber glass cartridge with a sterile active chamber containing PEG-INTRON powder and a diluent chamber containing Sterile Water for Injection, USP. The cartridge is provided in a pen device for reconstitution, dose preparation and subcutaneous administration. Following reconstitution of the powder with the diluent contained within the cartridge, each Redipen Single-dose Delivery System contains PEG-INTRON at strengths of either 50 mcg/0.5 mL, 80 mcg/0.5 mL, 120 mcg/0.5 mL or 150 mcg/0.5 mL for a single use.

The FDA on Jan. 19, 2001, granted marketing approval to PEG-INTRON(TM) (peginterferon alfa-2b) Powder for Injection as once-weekly monotherapy for the treatment of chronic hepatitis C in patients not previously treated with alpha interferon who have compensated liver disease and are at least 18 years of age.

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On June 22, 2001, Schering-Plough reported, among other things, that the FDA had issued inspection reports (Form FDA-483s) which cited some continuing and some additional deficiencies concerning compliance with current Good Manufacturing Practices. Schering-Plough reported that it cannot predict the outcome of the issues cited in the inspection reports or the timing of any resolution.

Near the end of June 2001 we were made aware that certain references in certain of these inspection reports relate to ribavirin, which is manufactured in Schering-Plough's facilities. The supplemental BLA and NDA for ribavirin that

Schering-Plough submitted to the FDA in February 2001 and November 2000, respectively, are currently under active FDA review. The February 2001 supplemental BLA seeks marketing

approval for PEG-INTRON for use in combination therapy with REBETOL Capsules (ribavirin) for the treatment of adult patients with chronic hepatitis C. The November 2000 supplemental NDA seeks approval to market REBETOL separately for use in combination with INTRON A for the treatment of the same indication. Enzon cannot predict whether Schering-Plough's failure to resolve the deficiencies cited in these inspection reports could delay or otherwise impact the FDA's review of these applications.

Except for the historical information herein, the matters discussed in this Form 8-K include forward-looking statements that may involve a number of risks and uncertainties. Actual results may vary significantly based upon a number of factors which are described in the Company's Form 10-K, Form 10-K/A, Form 10-Q's and Form 8-Ks on file with the SEC, including without limitation, risks in obtaining and maintaining regulatory approval for indications and expanded indications, market acceptance of and continuing demand for Enzon's products and the impact of competitive products and pricing.

#### 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: July 16, 2001

ENZON, INC.

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(Registrant)

By: /s/ KENNETH J. ZUERBLIS

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Kenneth J. Zuerblis  
Vice President, Finance, Chief Financial  
Officer and Secretary