DUSA PHARMACEUTICALS INC
Form 8-K
September 12, 2006

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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): September 12, 2006

DUSA PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

NEW JERSEY	0-19777	22-3103129
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification Number)

25 UPTON DRIVE
WILMINGTON, MASSACHUSETTS 01887
(Address of principal executive offices, including ZIP code)

(978) 657-7500
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

[ ] Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

[ ] Soliciting material pursuant to Rule 14a-12 under the Securities Act (17 CFR 240.14a-12)

[ ] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

[ ] Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

ITEM 8.01 - OTHER EVENTS.

DUSA Pharmaceuticals, Inc. ("DUSA") has been informed that Actavis Totowa, LLC received a warning letter from the U.S. Food and Drug Administration ("FDA") regarding certain regulatory observations. Actavis Totowa, formerly known as Amide Pharmaceuticals, Inc., is the contract manufacturer of Nicomide(R). The primary observations noted in the warning letter were not related to Nicomide(R). However, with respect to Nicomide(R) and certain other products manufactured by Actavis Totowa, the FDA has requested that the manufacturer

provide a copy of the labeling and information providing the basis for an exemption from the drug approval requirements. The FDA regulates such products under the compliance policy guide entitled, "Marketed New Drugs without Approved NDAs or ANDAs." DUSA is working with the manufacturer in order to respond appropriately to the FDA.

Nicomide(R) is one of the key products DUSA acquired from Sirius Laboratories, Inc. in connection with our merger completed in March, 2006. Nicomide(R) is an oral prescription vitamin supplement.

In addition, as DUSA has previously stated, certain of the Sirius products acquired in connection with the merger must meet certain minimum manufacturing and labeling standards established by the FDA and applicable to products marketed without approved marketing applications. FDA regulates such products under its marketed unapproved drugs compliance policy mentioned above. Under this policy, FDA recognizes that certain unapproved products, based on the introduction date of their active ingredients and the lack of safety concerns, have been marketed for many years and, at this time, will not be the subject of any enforcement action. We believe that so long as we comply with applicable manufacturing and labeling standards we will be consistent with FDA's current enforcement policy. There can be no assurance that the FDA will continue this policy or not take a contrary position with any individual products. If the FDA were to do so, we may be required to seek FDA approval for these products, market these products as over-the-counter products or as dietary supplements under applicable legislation, or withdraw such products from the market.

Except for historical information this report contains certain forward-looking statements that involve known and unknown risk and uncertainties, which may cause actual results to differ materially from any future results, performance or achievements expressed or implied by the statements made. These forward-looking statements relate to our beliefs regarding the applicability of FDA's guidance to our products and potential ramifications thereof. Furthermore, the factors that may cause differing results include the regulatory process and environment, actions or inactions of third-parties, sources of funding, maintenance of its patent portfolio and other risks identified in DUSA's SEC filings from time to time.

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.

DUSA PHARMACEUTICALS, INC.

By: /s/ D. Geoffrey Shulman

D. Geoffrey Shulman, MD, FRCPC
Chairman of the Board and
Chief Executive Officer

Dated: September 12, 2006