MOMENTA PHARMACEUTICALS INC
Form 8-K
November 06, 2007

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): **November 6, 2007 (November 6, 2007)**

Momenta Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**000-50797**	**04-3561634**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

675 West Kendall Street, Cambridge, MA	**02142**
(Address of Principal Executive Offices)	(Zip Code)

(617) 491-9700

(Registrant s telephone number, including area code)

Not applicable

(Former Name or Former Address, if Changed Since Last Report)

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):

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

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

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

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

Item 8.01. **Other Events.**

On November 6, 2007, Momenta Pharmaceuticals, Inc., a Delaware corporation (the Company), announced that its collaboration partner, Sandoz Inc. (Sandoz), a division of Novartis, had received a letter from the U.S. Food and Drug Administration (the FDA) on November 5, 2007, stating that the Abbreviated New Drug Application (ANDA) for M-Enoxaparin Sodium Injection, the Company s technology-enabled generic version of Lovenox®, a widely prescribed low molecular weight heparin, is not approvable.

The FDA s action letter indicated that the ANDA for M-Enoxaparin was not approvable in its current form because the application does not adequately address the potential for immunogenicity of the drug product. The FDA recommended in its letter that the Company and Sandoz meet with the Office of Generic Drugs to determine what additional information should be provided to adequately address this concern. Sandoz and the Company are working together to address the FDA s questions and determine the information necessary to obtain approval of M-Enoxaparin.

SIGNATURE

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.

MOMENTA PHARMACEUTICALS, INC.

Date: November 6, 2007

By: /s/ Craig A. Wheeler

Craig A. Wheeler
Chief Executive Officer
(Principal Executive Officer)