AKORN INC
Form 8-K
April 02, 2007

UNITED STATES
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: March 29, 2007
(Date of Earliest Event Reported)

Akorn, Inc.
(Exact Name of Registrant as Specified in its Charter)

Louisiana	**0-13976**	**72-0717400**
(State or other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

2500 MILLBROOK DRIVE
BUFFALO GROVE, ILLINOIS 60089
(Address of principal executive offices, zip code)

(847) 279-6100
(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):

o Written communication 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 communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
o Pre-commencement communication pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240. 13e-4(c))

Item 8.01 Other Events.

On March 29, 2007, the Company received an FDA Warning Letter (the Letter) following a routine inspection of our Decatur, Illinois manufacturing facility conducted from September 12 through September 29, 2006. The Letter cited significant deviations from current Good Manufacturing Practice (cGMP) Regulations. According to the Letter, failure to promptly correct the violations cited in the Letter may result in legal action without further notice, including, without limitation, seizure and injunction. The FDA may withhold approval of pending new drug applications listing the Decatur manufacturing facility as a manufacturer until the violations are corrected. The Letter states that a reinspection may be necessary.

Within 15 working days of receipt of the Letter, we are to notify the FDA in writing of the specific steps that we have taken to correct violations. If we cannot complete corrective action within that time we will state the reason for the delay and the time we need to complete the correction. We intend to complete our corrective action within the time period indicated, but will notify the FDA if we require more time to do so.

We believe that the Letter will delay the in-service date for our lyophilizers, and the launch of IC-Green. The impact on revenues in the first half of 2007 due to lack of IC-Green sales will be approximately $2,000,000. The Company will immediately seek a contract manufacturer for IC-Green. We anticipate no other significant adverse impact on our business.

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.

Akorn, Inc.

By: /s/ Jeffrey A. Whitnell
Jeffrey A. Whitnell
Chief Financial Officer, Treasurer and Secretary

Date: April 2, 2007