

CARDINAL HEALTH INC
Form 8-K
February 17, 2009

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 (Date of earliest event reported): February 17, 2009

Cardinal Health, Inc.

(Exact name of registrant as specified in its charter)

Ohio
(State or other jurisdiction

of incorporation)

1-11373
(Commission File Number)

31-0958666
(IRS Employer

Identification No.)

Edgar Filing: CARDINAL HEALTH INC - Form 8-K

7000 Cardinal Place, Dublin, Ohio
(Address of principal executive offices)

43017
(Zip Code)

(614) 757-5000

(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 Exchange 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 7.01 Regulation FD Disclosure

A copy of a news release announcing the Amended Consent Decree (as defined below) is included as Exhibit 99.1 to this report.

Item 8.01 Other Events

As previously reported, in February 2007, Cardinal Health 303, Inc., a subsidiary of Cardinal Health, Inc. that manufactures and sells infusion pumps in the United States (Cardinal Health 303), and the U.S. Food and Drug Administration (the FDA) agreed to a Consent Decree for Condemnation and Permanent Injunction (the Consent Decree) related to the Alaris SE pumps manufactured or sold in the United States. The FDA and Cardinal Health 303 have amended the Consent Decree (as amended, the Amended Consent Decree) to include all infusion pumps manufactured by or for Cardinal Health 303. The Amended Consent Decree is expected to be filed shortly with the U.S. District Court for the Southern District of California and is subject to approval by the District Court.

The FDA alleges in the Amended Consent Decree that based on a January 2008 inspection, certain of Cardinal Health 303 s infusion pumps do not satisfy the standards of the Federal Food, Drug and Cosmetic Act (the Act). Without admitting the allegations contained in the Amended Consent Decree, and in addition to the requirements of the original Consent Decree, Cardinal Health 303 has agreed, among other things: (i) within 60 days of entry into the Amended Consent Decree, to submit a corrective action plan to the FDA to bring Alaris System pumps and all other infusion pumps in use in the U.S. market into compliance with the Act; (ii) within 100 days of entry into the Amended Consent Decree, to have an independent expert perform a comprehensive inspection of Cardinal Health 303 s infusion pump facilities and certify whether its infusion pump operations are in conformity with the Quality System Regulation and certain other provisions of the Act; and (iii) within 100 days of entry into the Amended Consent Decree, to have an independent recall expert inspect Cardinal Health 303 s recall procedures and all ongoing recalls involving its infusion pumps and certify whether the recall procedures are in compliance with the Act and whether Cardinal Health 303 should take any further remedial actions with respect to any recalls involving its infusion pumps.

The Amended Consent Decree does not apply to intravenous administration sets and accessories. Furthermore, it does not prohibit Cardinal Health 303 from continuing to manufacture, market and sell infusion pumps (other than the Alaris SE pumps, which were covered under the original Consent Decree). A form of the Amended Consent Decree is filed as Exhibit 99.2 to this report and the foregoing description is qualified by reference to the full text of the agreement set forth in this exhibit.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

99.1 News release issued by Cardinal Health, Inc. on February 17, 2009 announcing the Amended Consent Decree

99.2 Form of Amended Consent Decree for Condemnation and Permanent Injunction

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.

Cardinal Health, Inc.
(Registrant)

Date: February 17, 2009

By: /s/ Ivan K. Fong
Name: Ivan K. Fong
Title: Chief Legal Officer and Secretary

- 3 -

EXHIBIT INDEX

- 99.1 News release issued by Cardinal Health, Inc. on February 17, 2009 announcing the Amended Consent Decree
- 99.2 Form of Amended Consent Decree for Condemnation and Permanent Injunction