CHIRON CORP
Form 8-K
October 05, 2004

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): **October 5, 2004**

Chiron Corporation

(Exact name of registrant as specified in its charter)

Delaware	**0-12798**	**94-2754624**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

4560 Horton Street, Emeryville, CA	**94608**
(Address of principal executive offices)	(Zip Code)

Registrant s telephone number, including area code **(510) 655-8730**

N/A

(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 October 5, 2004, Chiron Corporation announced via press release that the UK regulatory body, the Medicines and Healthcare Products Regulatory Agency (MHRA) has temporarily suspended the Company s license to manufacture Fluvirin® influenza virus vaccine and that the Company does not expect to release any of its Fluvirin® product during the 2004-2005 influenza season. Excerpts from the press release are set forth below:

NEWS RELEASE

For Immediate Release

Contacts:
Chiron Corporate Communications & Investor Relations
Media: (510) 923-6500
Investors: (510) 923-2300

CHIRON WILL NOT SUPPLY FLUVIRIN® INFLUENZA VIRUS VACCINE FOR 2004-2005 INFLUENZA SEASON

UK regulatory authority suspends manufacturing license and denies product release

Chiron to hold investor conference call/audio webcast at noon EDT

EMERYVILLE, Calif., October 5, 2004 Chiron Corporation (NASDAQ: CHIR) announced that the UK regulatory body, the Medicines and Healthcare Products Regulatory Agency (MHRA), has today temporarily suspended the company s license to manufacture Fluvirin® influenza virus vaccine in its Liverpool facility, preventing the company from releasing any of the product during the 2004-2005 influenza season. Chiron has not released any Fluvirin into any territory, and therefore there is no requirement to recall or withdraw any vaccine.

Chiron deeply regrets that we will be unable to meet public health needs this season. We take our responsibility to protect human health very seriously, said Howard Pien, president and CEO of Chiron. Chiron believes in the value of influenza vaccination, and we are committed to taking all necessary actions to ensure an adequate vaccine supply for the 2005-2006 influenza season.

As Chiron conducted its internal quality assurance confirmatory testing in recent weeks, MHRA, in its capacity as the Liverpool production facility s local regulatory authority, reviewed the test data and the manufacturing processes at the facility. As noted in the company s September 28, 2004, press release, Chiron anticipated that the regulatory review process would be satisfactorily completed in time to allow release of Fluvirin in

early October. However, MHRA has asserted that Chiron s manufacturing process does not comply with UK Good Manufacturing Practices regulations and has suspended the company s Liverpool facility license to manufacture influenza vaccine for three months. Chiron has initiated discussions with the MHRA to determine the appropriate corrective actions.

As a result of the license suspension, Chiron does not expect to record any sales of Fluvirin for the 2004-2005 season.

In August, Chiron announced a delay in providing Fluvirin for the 2004-2005 influenza season. Chiron has communicated regularly with the U.S. Food and Drug Administration (FDA), which has regulatory oversight for vaccines marketed in the United States, and U.S. Centers for Disease Control and Prevention (CDC), which makes recommendations for influenza vaccination through its National Immunization Program (NIP) and the Advisory Committee on Immunization Practices (ACIP). Chiron has informed the FDA, CDC and the UK Department of Health of the current situation. Chiron had previously expected to provide nearly half the U.S. supply for the 2004-2005 influenza season and is discussing potential impact with FDA and CDC. In the United Kingdom, where Fluvirin typically accounts for approximately 20 percent of the influenza vaccine market, Chiron plans to make up a significant proportion of this supply with vaccines that are produced at its other European sites and approved for use in the United Kingdom (but not the United States). Chiron plans to continue to work with the CDC and the U.S. Food and Drug Administration s Center for Biologics Evaluation and Research (CBER) in preparation for the 2005-2006 influenza season.

Our manufacturing and quality staff have worked hard to resolve what we viewed as a problem limited in scope to a few batches, and we believe our quality assurance confirmatory testing demonstrates that the Fluvirin doses we anticipated releasing are safe. While the MHRA s conclusions are unexpected, we respect the regulatory authority s judgment, said John Lambert, president of Chiron Vaccines. We apologize unreservedly to the public and our customers for being unable to meet our commitments this year.

This news release contains forward-looking statements, including statements regarding the supply of Fluvirin that Chiron expects to deliver to the U.S. market in future influenza seasons, ..., sales growth versus prior periods, product development initiatives, and new product marketing. These forward-looking statements involve risks and uncertainties and are subject to change. No assurances can be given that additional issues with respect to Fluvirin or Chiron s manufacturing generally will not arise in the future or that the MHRA will not further suspend or revoke the license to Chiron s Liverpool facility . Many factors could cause actual results and developments to differ materially from those expressed or implied by these forward-looking statements, including, among others, additional adverse developments resulting from investigations or discussions with or actions taken or required by the MHRA, FDA, U.S. Department of Health and Human Services, or CDC. In addition, a full discussion of the company s operations and financial condition, including factors that may affect its business and future prospects, is contained in documents the company has filed with the SEC, including the form 10-Q for the quarter ended June 30, 2004, and the form 10-K for the year ended December 31, 2003, and will be contained in all subsequent periodic filings made with the SEC. These documents identify other important factors that could cause the company s actual performance to differ from the expectation expressed or implied by these

forward-looking statements, including the outcome of clinical trials, regulatory review and approvals, manufacturing and testing capabilities, pricing pressures, intellectual property protections and defenses, litigation, stock-price volatility, and marketing effectiveness. In particular, there can be no assurance that Chiron will timely maintain anticipated levels of profitability, increase sales of existing products, successfully develop and receive approval to market new products, or achieve market acceptance for such new products. In addition, the company may engage in business opportunities, the successful completion of which are subject to certain risks, including shareholder and regulatory approvals and the integration of operations.

Consistent with SEC Regulation FD, we do not undertake an obligation to update the forward-looking information we are giving today.

NOTE: Fluvirin is a trademark of Chiron Corporation.

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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.

CHIRON CORPORATION
(Registrant)

Date: October 5, 2004

By: /s/ Ursula B. Bartels
Ursula B. Bartels
Vice President and
General Counsel