GENOMIC HEALTH INC
Form 8-K
January 27, 2006

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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): January 24, 2006
GENOMIC HEALTH, INC.
(Exact name of registrant as specified in its charter)

Delaware	**000-51541**	**77-0552594**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

301 Penobscot Drive, Redwood City, California	**94063** (Zip Code)

(Address of principal executive offices)

Registrant s telephone number, including area code: **(650) 556-9300**

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:

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))

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Item 8.01 Other Events.

Genomic Health, Inc. (the Company) announced today that it has received a letter from the Food and Drug Administration (the FDA) regarding Onco*type* DX , the Company s genomic-based test for early stage breast cancer patients. The letter invited the Company to meet with the FDA to discuss the nature and appropriate regulatory status of the Company s technology and the least burdensome ways that the Company may fulfill any FDA premarket review requirements that may apply. The Company plans to meet with the FDA in the near future.

Onco*type* DX was launched in 2004 and to date over 2,000 physicians have utilized the test in the treatment planning for more than 7,000 breast cancer patients. Clinical laboratory services like Onco*type* DX are currently regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as administered through the Centers for Medicare/Medicaid Services, as well as by applicable state laws. The test is performed at the Company s Redwood City central reference laboratory, which is accredited under CLIA and the College of American Pathology (CAP). The Company s licensed clinical laboratory and the Onco*type* DX test cleared all required CLIA evaluations before the first patient test was run and results reported.

As previously disclosed in the Company s SEC filings, in December 2004, the FDA contacted the Company regarding the regulatory status of Onco*type* DX and the Company subsequently engaged in informal communications with the FDA. In early 2005, the FDA indicated that it was considering whether Onco*type* DX may be subject to FDA premarket review.

A copy of the letter from the FDA is attached hereto as Exhibit 99.1.

Forward Looking Statements.

This current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding the Company s actions in response to the FDA. Forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially, including the results of discussions with the FDA, the status of regulation by the FDA of the Company s products and the other risks and uncertainties set forth in the Company s filings with the Securities and Exchange Commission, including its Quarterly Report on Form 10-Q for the quarter ended September 30, 2005. These forward-looking statements speak only as of the date hereof. The Company disclaims any obligation to update these forward-looking statements.

Item 9.01 Financial Statements and Exhibits.

(c) Exhibits

Exhibit No.	Description
99.1	Letter from the Food and Drug Administration dated January 23, 2006

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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.

Dated: January 26, 2006

GENOMIC HEALTH, INC.

By: /s/ G. Bradley Cole
Name: G. Bradley Cole
Title: Chief Financial Officer

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Exhibit Index

Exhibit No.	Description
99.1	Letter from the Food and Drug Administration dated January 23, 2006