

EXELIXIS INC
Form 8-K
December 04, 2006

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): December 1, 2006

EXELIXIS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction

of incorporation)

0-30235
(Commission

File Number)
170 Harbor Way

P.O. Box 511

South San Francisco, California 94083-0511

(Address of principal executive offices, including zip code)

(650) 837-7000

(Registrant's telephone number, including area code)

04-3257395
(IRS Employer

Identification No.)

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)

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- “ 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))
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Item 8.01 Other Events.

On December 1, 2006, in a discussion with representatives from the Food and Drug Administration (the FDA), Exelixis, Inc. (the Company) agreed with the FDA's determination to place the XL999 clinical trial program on a partial clinical hold thereby formalizing the decision made by the Company on November 1, 2006 to suspend enrollment of new patients into the XL999 program. Also, consistent with the Company's decision on November 1, 2006, the FDA agreed with the Company that patients who are currently on study may continue to receive XL999 so long as they are free of adverse events or disease progression.

As previously reported, on November 1, 2006, the Company suspended enrollment of new patients into the XL999 clinical trial program due to an apparent increase in the rate of serious cardiovascular events in the month of October compared to the period prior to October.

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.

EXELIXIS, INC.

Dated: December 4, 2006

By: /s/ Christoph Pereira
Christoph Pereira
Vice President, Legal Affairs and Secretary