DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021343/S-020 and 3 others

SUPPLEMENT APPROVAL

sanofi-aventix U.S. LLC
Attention: Gregory Urbancik
U.S. Regulatory Affairs, Marketed Products
55 Corporate Drive
Bridgewater, NJ 08807

Dear Mr. Urbancik:

Please refer to your Supplemental New Drug Application (sNDA) dated March 24, 2011, received March 24, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Eligard (leuprolide acetate) injectable suspension for the following:

Application	Supplement	Drug Name
NDA 021343	S-020	Eligard (leuprolide acetate) injectable suspension, 7.5 mg
NDA 021379	S-016	Eligard (leuprolide acetate) injectable suspension, 22.5 mg
NDA 021488	S-017	Eligard (leuprolide acetate) injectable suspension, 30 mg
NDA 021731	S-013	Eligard (leuprolide acetate) injectable suspension, 45 mg

This "Changes Being Effected" supplemental new drug application provides for adding "in men" in the WARNINGS AND PRECAUTIONS section of the HIGHLIGHTS as requested in our March 11, 2011, supplement request letter and described below (additions are underlined).

- Cardiovascular diseases: Increased risk of myocardial infarction, sudden cardiac death and stroke has been reported <u>in men</u>. Monitor for cardiovascular disease and manage according to current clinical practice. (5.4)

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling text for the package insert, with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Susan Jenney, Regulatory Project Manager, at (301) 796-0062.

Sincerely,

{See appended electronic signature page}

Katherine Fedenko, M.S., C.R.N.P.
Deputy Director for Safety
Division of Drug Oncology Products
Office of Oncology Drug Products
Center of Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

KATHERINE M FEDENKO
04/08/2011