DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-343/S-015
NDA 21-488/S-010
NDA 21-379/S-010
NDA 21-731/S-005

Sanofi-Aventis U.S., LLC
300 Somerset Corporate Boulevard,
P.O. Box 6977
Bridgewater, NJ 08807-0977

Attention: Dr. Sanjukta Bhaduri
Senior Manager, US Regulatory Affairs Marketed Products

Dear Dr. Bhaduri:

Please refer to your supplemental new drug applications dated May 31, 2006, received June 1, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ELIGARD ® (leuprolide acetate) for Injectable Suspension, 7.5 mg, 22.5 mg, 30 mg, and 45 mg.

These prior approval supplemental new drug applications provide for the combination of the package inserts derived from the four approved strengths (7.5 mg, 22.5 mg, 30 mg, and 45 mg) of ELIGARD® (leuprolide acetate) for Injectable Suspension into one package insert. These prior approval supplements also provide for the addition of "pituitary apoplexy" and the revision of the "pituitary apoplexy" language in the ADVERSE REACTION Section of the label at the behest of the Division of Reproductive and Urologic Drug Products.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert).

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text/submitted labeling dated May 31, 2006.

Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

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

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

If you have any questions, call Kim J. Robertson, Consumer Safety Officer, at (301) 796-1441.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D.
Division Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure (labeling)

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

/s/

Robert Justice
11/8/2007 06:41:51 PM