DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-343/S-004
NDA 21-379/S-002
NDA 21-488/S-002

Sanofi~Synthelabo
Attention: Eileen De Micco, M.A.
90 Park Avenue
New York, NY 10016

Dear Ms. De Micco:

Please refer to your supplemental new drug applications dated August 19, 2003 received August 20, 2003 for NDA 21-343/S-004, NDA 21-379/S-002, and NDA 21-488/S-002 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Eligard® 7.5 mg, Eligard® 22.5 mg, and Eligard® 30 mg (leuprolide acetate for injectable suspension).

These "Special Supplement-Changes Being Effected" supplemental new drug applications provide for revisions to the Package Inserts (PI)s, wherein you have incorporated instructional language on the dosing and the administration of the drug products.

We have completed our review of these applications and they are approved as written, effective on the date of this letter.

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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

FDA also acknowledges that these supplements contain final printed labeling (FPL) for each of the above identified NDAs.

We have reviewed the labeling that you submitted and we find it acceptable.

If you have any questions, please call Nita Crisostomo, RN, BSN, Regulatory Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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

/s/

Daniel A. Shames

1/12/04 10:40:21 AM