



NDA 21-343/S-001

Sanofi-Syhelabo Inc.
Attention: Jessica M. Dunn-Skorupski
Regulatory Specialist, Drug Regulatory Affairs
90 Park Avenue
New York, NY 10016

Dear Ms. Dunn-Skorupski:

Please refer to your supplemental new drug application dated March 8, 2002, received March 11, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Eligard™ 7.5 mg (leuprolide acetate for injectable suspension).

This "Changes Being Effected in 30 days" supplemental new drug application provides for revised syringe, pouch and carton labels to include the addition of the expiration date on all of the labeling components, the relocation of the NDC number to the top third of the labeling components, and the addition of internal coding.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (immediate container and carton labels submitted March 8, 2002). Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Jeanine Best, M.S.N., R.N., Regulatory Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
Acting 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
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/s/

Daniel A. Shames
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