DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-088/S-015

Alza Corporation
Attn: Janne Wissel
Sr. Vice President, Operations
1900 Charleston Road
P.O. Box 7210
Mountain View, CA 94039-7210

Dear Ms. Wissel:

Please refer to your supplemental new drug application dated April 18, 2002, received April 22, 2002 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Viadur® (leuprolide acetate implant).

This "Changes Being Effected" supplemental new drug application provides for proposed physician and patient insert, the instruction booklet, and a new instruction sheet to be added to the kit.

We completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text. The final printed labeling (FPL) must be identical to the labeling text for the physician and patient package insert submitted on April 18, 2003.

Please submit copies of FPL, electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavyweight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-088/S-015". Approval of this submission by FDA is not required before the labeling is used.

In addition, as required by 21 CFR 314.550, submit three copies of all promotional materials including promotional labeling and advertisements that you intend to use within 120 days following approval of this product. Submit all proposed materials in draft or mock up form, not final print. Send one copy to the Division of Reproductive and Urologic Drug Products, HFD-580 and two copies of both the promotional materials and the proposed package insert directly to:

Division of Drug Marketing, Advertising
And Communications, HFD-42
Food and Drug Admnistration
5600 Fishers Lane
Rockville, MD 20857

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).

If you have any questions, please call Archana Reddy, 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

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