



NDA 21-333/S-001

Ferring Pharmaceuticals Inc.
Attention: Michael I. Bernhard, Ph.D.
Senior Director, Regulatory Affairs
400 Rella Boulevard, Suite 300
Suffern, NY 10901

Dear Dr. Bernhard:

Please refer to your supplemental new drug application dated October 25, 2002, received October 28, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for DESMOPRESSIN ACETATE Nasal Spray, 0.1 mg/mL.

We acknowledge receipt of your submissions dated May 9 and June 4, 2003.

Your submission of May 9, 2003, constituted a complete response to our April 28, 2003, action letter.

This supplemental new drug application provides for the addition of a proprietary name, Minirin.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below.

- The established name must appear in conjunction with the established name at least once on each page of the package insert per 21 CFR 201.10(g).

The final printed labeling (FPL) must be identical, and include the minor editorial revision indicated, to the enclosed labeling (text for the package insert and text for the patient package insert) and submitted labeling (immediate container and carton labels submitted October 25, 2002) (enclosed). These revisions are terms of the approval of this application.

Please submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDAs*. 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 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-333/S-001." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
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, call Enid Galliers, Chief, Project Management Staff, at (301) 827-6429.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products (HFD-510)
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures:

Package Insert (agreed upon text)
Patient Package Insert (agreed upon text)
Vial Label
Carton (Shelf Pack)

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

/s/

David Orloff
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