DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-333

Ferring Pharmaceuticals Inc.
Attention: Ronald V. Nardi, Ph.D.
Executuve Vice President and Chief Scientific Officer
120 White Plains Road, Suite 400
Tarrytown, New York 10591

Dear Dr. Nardi:

Please refer to your new drug application (NDA) dated October 27, 2000, received November 3, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Desmopressin Acetate Nasal Spray.

We acknowledge receipt of your submissions dated July 14 and 18, 2002. Your submission of July 14, 2002, constituted a complete response to our August 29, 2001, action letter.

This new drug application provides for the use of a refrigerated formulation of Desmopressin Acetate Nasal Spray for primary nocturnal enuresis and for the management of central cranial diabetes insipidus.

We completed our review of this application, as amended. 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 submitted labeling (package insert submitted July 14, 2002 [enclosed], patient package insert (submitted July 14, 2002 [enclosed], immediate container and carton labels submitted July 18, 2002). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDA.* Alternatively, you may submit 20 copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 21-333." Approval of this submission by FDA is not required before the labeling is used.

Please note, if you choose to use a proprietary name for this product, the name and its use in the label must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit any proprietary name to the Agency for our review prior to its implementation.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We are waiving the pediatric study requirement for primary nocturnal enuresis in children less than 6 years. For central diabetes insipidus treatment in children 0 to 3 months, we are deferring the pediatric studies requirement. We request that you submit published literature to evaluate whether data are adequate to support this population.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit 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, Maryland 20857

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

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 Steve McCort, Regulatory Project Manager, at (301) 827-6415.

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

ENCLOSURE

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

9/16/02 02:57:47 PM