NDA 21-008

Novartis Pharmaceutical Corporation
Attention: Ms. Eileen Ryan
Associate Director, Drug Regulatory Affairs
59 Route 10
East Hanover, NJ 07936-1080

Dear Ms. Ryan:

Please refer to your new drug application (NDA) dated May 29, 1998, received May 29, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sandostatin LAR® (octreotide acetate for injectable suspension) Depot, 10, 20, 30 mg.

We acknowledge receipt of your submissions dated July 16 and 31, August 17, September 9, 10, 11, and 28, October 9 (2), 16, 19 (2), 20, 21, 22, 23(2), 28 and 30, November 3, 5, 10, 13 (2), 24 (2) and 25, 1998.

This new drug application provides for the use of Sandostatin LAR® (octreotide acetate for injectable suspension) Depot for the reduction of growth hormone and IGF-1 in acromegaly, the suppression of severe diarrhea and flushing associated with malignant carcinoid syndrome and for the treatment of the profuse watery diarrhea associated with VIPoma (vasoactive intestinal peptide tumor).

We have completed the review of this application, as amended, 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 agreed upon labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed draft labeling (package insert submitted November 24, 1998, immediate container and carton labels submitted October 21, 1998). 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 20 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 heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 21-008." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your Phase 4 commitments specified in your submission dated November 24, 1998. These commitments, along with any completion dates agreed upon, are listed below:

Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. If an IND is not required to meet your Phase 4 commitments, please submit protocols, data and final reports to this NDA as correspondence.

In addition, under 21 CFR 314.82(b)(2)(vii), we request that you include a status summary of each commitment in your annual report to this NDA. The status summary should include the number of patients entered in each study, expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

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.

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-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

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, please contact Ms. Jena Weber, Project Manager, at (301) 827-6422.

Sincerely,

Solomon Sobel, M.D.
Director
Division of Metabolic and Endocrine Drug Products

Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE