DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-667/S-044

Novartis Pharmaceuticals Corporation
Attention: Elizabeth McCartney
Assistant Director, Global Regulatory CMC
One Health Plaza
East Hanover, New Jersey 07936-1080

Dear Ms. McCartney:

Please refer to your supplemental new drug application dated September 19, 2002, received September 20, 2002, submitted under section 505 (b) of the Federal Food, Drug, and Cosmetic Act for Sandostatin (octreotide acetate) Injection available as ampuls and vials.

We acknowledge receipt of your submissions dated December 11 and 13, 2002.

This supplement proposes a new site of manufacture of vials of Sandostatin Injection (5 mL multi-dose vials in 2 strengths, containing 200 mcg/mL and 1000 mcg/mL). The new site of manufacture, primary packaging/labeling, and analytical testing is the Novartis Pharma Stein AG, Switzerland facility. Also included is the withdrawal of the current approved site of manufacture, Novartis Pharma AG Basle, Switzerland, and the current approved site of packaging and analytical testing, Novartis East Hanover, New Jersey facility, pending approval of this supplement. In conjunction with the new manufacturing site there are changes to the batch size and the container/closure system.

We completed our 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, this 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, immediate container, and carton labels submitted September 19, 2002).

Please submit the 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 heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 19-667/S-044." Approval of this submission by FDA is not required before the labeling is used.

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

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, HF-2
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 Su Yang, Regulatory Project Manager, at (301) 827-6385.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
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/

David Orloff

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