DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-667/S-042

Novartis Pharmaceuticals Corporation
Attention: Elizabeth McCartney
Associate 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 January 9, 2002, received January 11, 2002, submitted under section 505 (b) of the Federal Food, Drug, and Cosmetic Act for Sandostatin (octreotide acetate) Injection.

We acknowledge receipt of your submission dated December 10, 2002. Your submission of October 11, 2002, constituted a complete response to our May 7, 2002, action letter.

This prior approval supplement provides for the following (for ampuls only):

1) A new manufacturing site (Novartis Pharma Stein AG, Switzerland) for the drug product, and associated labeling revisions to the package insert, container, and carton labels
2) A change in batch size
3) The qualification of a new analytical testing site for the drug product

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 draft labeling submitted on the following dates:

1) Container labels - October 11, 2002
2) Carton labels - January 16, 2002 for 20-count and October 11, 2002 for 10-count

The proposed revisions to the package insert were inadvertently approved with supplement-044 on January 17, 2003.

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-042." 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

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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 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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