**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-667/S-054

Novartis Pharmaceuticals Corporation
Attention: Vincent De Stefano
Associate Director, Drug Regulatory Affairs
One Health Plaza
East Hanover, NJ 07936-1080

Dear Mr. De Stefano:

Please refer to your supplemental new drug application dated November 5, 2007, received November 5, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sandostatin Injection (octreotide acetate).

We acknowledge receipt of your submissions dated July 18 and August 13, 2008.

This "Changes Being Effected" supplemental new drug application provides for revisions to the following sections of the package insert: Precautions (General, Pregnancy Category B and Nursing Mothers subsections), Overdosage and How Supplied (Storage subsection).

We have 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.

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
Food and Drug Administration
Suite 12B05
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 Jennifer Johnson, Regulatory Project Manager, at (301) 796-2194.

Sincerely,

*{See appended electronic signature page}*

Mary H. Parks, M.D.
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: Package Insert

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/s/

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Mary Parks

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