DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-008/S-007

Novartis Pharmaceuticals Corporation
Attention: Martha Propsner
Associate Director, Drug Regulatory Affairs
One Health Plaza
East Hanover, New Jersey 07936-1080

Dear Ms. Propsner:

Please refer to your supplemental new drug application dated November 18, 2002, received November 20, 2002, submitted under section 505 (b) of the Federal Food, Drug, and Cosmetic Act for Sandostatin LAR Depot (octreotide acetate for injectable suspension).

This supplemental application, submitted as "Supplement - Changes Being Effected in 30 days" supplement, proposes a change in the needle gauge provided with the product kits from 20 to 19 to minimize the incidence of clogging.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling [(FPL) PI, Carton Labels (10, 20, 30 mg),(b)(4)---------- Instruc tion Booklet-Product Kit, and Instruct---------- on] submitted on November 18, 2002.

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 Holly Wieland, Project Manager, at (301) 827-6410.

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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