DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-008/S-015

Novartis Pharmaceuticals Corporation
Attention: Shanthi Ganeshan, PhD
Associate Director, Drug Regulatory Affairs
Building 105/ Room 3W182
East Hanover, NJ 07936

Dear Dr. Ganeshan:

Please refer to your supplemental new drug application dated April 13, 2004, received April 14, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sandostatin LAR Depot (octreotide acetate) Injection 10, 20, and 30 mg.

This "Changes Being Effected" supplemental new drug application provides for the addition of a sticker to a previously approved patient instruction booklet to advise patients ". . . the syringe is no longer supplied with a cap." This supplemental application was submitted in response to Novartis **(b)(4)**

In an October 13, 2004, phone conversation between you and members of the review division, you notified us that patient instruction booklets containing the sticker were distributed only until July 2004, and that since that time you have distributed the currently approved booklet (product identifier #86000801) without a sticker.

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) submitted on April 12, 2004.

In addition, submit two copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send two copies of both the promotional materials and the package insert(s) directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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, call Holly Wieland, Regulatory 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, HFD-510
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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