DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19-667/S-058
NDA 21-008/S-023

SUPPLEMENT APPROVAL

Novartis Pharmaceuticals Corporation
Attention: Leslie A. Bennett, RAC
Senior Associate Director, Drug Regulatory Affairs
One Health Plaza
East Hanover, NJ 07936-1080

Dear Ms. Bennett:

Please refer to your supplemental new drug applications dated October 27, 2008, received October 27, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Sandostatin (octreotide acetate) Injection and Sandostatin LAR Depot Injection (octreotide acetate for injectable suspension).

We acknowledge receipt of your submissions to each application dated July 29, 2009.

These "Prior Approval" supplemental new drug applications provide for revisions to the Pediatric Use section of the package inserts, in response to our supplement request letter issued on September 18, 2008.

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the minor editorial revisions listed below. These revisions were discussed and agreed upon during a telephone conversation that took place between you and Jennifer Johnson, Regulatory Project Manager, on September 23, 2009, and provide for correcting inadvertent omissions from the approved labeling contained in the Sandostatin LAR Depot Injection package insert.

1. Insert the heading "8.7 Hepatic Impairment – Cirrhotic Patients" into the Full Prescribing Information: Contents section.
2. Insert the number "6.1.1" corresponding to the sub-heading "Acromegaly" under section 6.1, Clinical Studies Experience.
3. Insert the number "6.1.2" corresponding to the sub-heading "Carcinoid and VIPomas" under section 6.1, Clinical Studies Experience.
4. Insert the number "8.7" corresponding to the sub-heading "Hepatic Impairment – Cirrhotic Patients" under section 8, Use in Specific Populations.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to, except for including the revisions listed above, the enclosed labeling (text for the package insert) submitted on July 29, 2009. These revisions are terms of the NDA approval. For administrative purposes, please designate these submissions, "SPL for approved NDA 19-667/S-058" and "SPL for approved NDA 21-008/S-023".

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

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 inserts for Sandostatin Injection and Sandostatin LAR Depot Injection

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21008	SUPPL-23	NOVARTIS PHARMACEUTICALS CORP	SANDOSTATIN LAR(OCTREOTIDE ACETATE)DEPOT
NDA-19667	SUPPL-58	NOVARTIS PHARMACEUTICALS CORP	SANDOSTATIN INJECTION

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MARY H PARKS
01/25/2010