DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ANDA 76-313

MAR 28 2005

Bedford Laboratories™
Attention: Molly L. Rapp
300 Northfield Road
Bedford, OH 44146

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated December 14, 2001, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Octreotide Acetate Injection, 0.05 mg/mL (base), 0.1 mg/mL (base) and 0.5 mg/mL (base), packaged in 1 mL vials (Preservative-free).

Reference is also made to your amendments dated March 26, April 7, two for August 2, and August 30, 2004.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Octreotide Acetate Injection, 0.05 mg/mL (base), 0.1 mg/mL (base), and 0.5 mg/mL (base), to be bioequivalent and, therefore, therapeutically equivalent to the listed drug.

The listed drug product (RLD) referenced in your application, Sandostatin®, 0.05 mg/mL (base), 0.1 mg/mL (base), and 0.5 mg/mL (base), of Novartis Pharmaceuticals Corp, is subject to periods of patent protection. As noted in the agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book), U.S. Patent No. 5,753,618 (the '618 patent) is scheduled to expire on May 19, 2015.

Your application contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act to the '618 patent stating that this patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Octreotide

Acetate Injection, under this ANDA. Section 505(j)(5)(B)(iii)[1] of the Act provides that approval of an ANDA shall be made effective immediately unless an action is brought against Bedford Laboratories (Bedford) for infringement of the '618 patent that was the subject of the paragraph IV certification. This action must be brought before the expiration of 45 days from the date the notice you provided under paragraph (2)(B)(i) was received by the NDA/patent holder(s). You have notified the agency that Bedford complied with the requirements of section 505(j)(2)(B) of the Act and that no action for infringement of the '618 patent was brought against Bedford within the statutory 45-day period.

With respect to 180-day generic drug exclusivity, we note that Bedford was the first to submit a substantially complete ANDA with a paragraph IV certification. Therefore, with this approval, Bedford is eligible for 180-days of market exclusivity. This exclusivity is provided for under section 505(j)(5)(B)(iv) of the Act.[2]

With respect to the "first commercial marketing" trigger for the commencement of exclusivity, please refer to 21 CFR 314.107(c)(4). The Agency expects that you will begin commercial marketing of this drug product in a prompt manner. Please submit correspondence to your application stating the date you commence commercial marketing of this product, or the date of a decision of the court holding the relevant patent invalid, unenforceable or not infringed.

Under section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

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[1] Because information on the '618 patent was submitted before August 18, 2003, this reference is to a section of the Act as in effect prior to December 8, 2003, when the Medicare Prescription Drug, Improvement and Modernization Act (MMA) (Public Law 108-173) was enacted. See MMA § 1101(c)(3).

[2] Because your ANDA was filed before the date of enactment of the MMA on December 8, 2003, this reference is to a section of the Act as in effect prior to December 8, 2003. See MMA § 1102(b)(1). Note that because in this case there is no possibility of a court decision (see section 505(j)(5)(B)(iv)(II) as in effect prior to December 8, 2003), first commercial marketing is the only action by which exclusivity can begin to run.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

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

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research