DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 75-959

Food and Drug Administration
Rockville MD 20857

NOV 21 2005

SICOR Pharmaceuticals, Inc.
Attention: Rosalie A. Lowe
Director, Regulatory Affairs
19 Hughes
Irvine, CA 92618-1902

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated August 31, 2000, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Octreotide Acetate Injection, 0.2 mg(base)/mL, and 1 mg(base)/mL, packaged in 5 mL multiple-dose vials.

Reference is also made to the Tentative Approval letter issued by this office on March 28, 2005, and to your amendments dated February 17, 2004; and August 24, and September 12, 2005.

The reference listed drug product (RLD) cited in your application, Sandostatin Injection, 0.2 mg(base)/mL, and 1 mg(base)/mL of Novartis Pharmaceuticals Corp., is subject to a period 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 this drug product, under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately unless an action was brought against Sicor Pharmaceuticals, Inc. (Sicor) for infringement of the '618 patent that was the subject of the paragraph IV certification. This action must have been brought against Sicor 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 Sicor complied with the requirements of section 505(j)(2)(B)[1] of the Act and that no action for infringement of the '618 patent was brought against Sicor within the statutory 45 day period.

Furthermore, as noted in the "Orange Book" with respect to the '618 patent, the exclusivity granted to Bedford Laboratories, upon approval of their ANDA for this drug product expired on November 20, 2005. Therefore, since Sicor has successfully addressed the patent and Bedford's exclusivity has expired, we can grant final approval to your application.

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, 0.2 mg(base)/mL and 1 mg (base)/mL, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug, Sandostatin Injection 0.2 mg(base)/mL and 1 mg(base)/mL, respectively, of Novartis Pharmaceuticals Corp.

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.

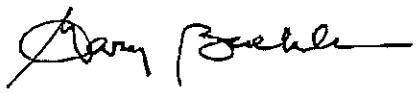
Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit,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

[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).

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

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