**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-800/S-011

Verus Pharmaceuticals, Inc.
1267 High Bluff Drive, Suite 200
San Diego, CA 92130

Attention: Steven Jensen
Senior Director, Regulatory Affairs

Dear Mr. Jensen:

Please refer to your supplemental new drug application dated August 25, 2006, received August 28, 2006 pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Twinject Auto-Injector (epinephrine injection, USP 1:1000) 0.3 and 0.15 mg.

We acknowledge receipt of your submissions dated, November 9 and December 22, 2006.

This supplemental new drug application provides for modifications to the Auto-Injector assembly components, harmonization of selected component colors, qualification of an alternate assembler, revision to batch release specifications/testing regimen and revisions to the carton and container, patient use instructions, and package insert to provide for a single label for both strengths.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (immediate container and carton labels submitted, August 25, 2006, patient use instructions, wrap labels, and package insert submitted, December 22, 2006).

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the submitted labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

Please submit either an electronic version or 20 paper copies of the FPL as soon as it is available (no more than 30 days after it is printed). If paper copies are submitted, individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-800/S-011**." Approval of this submission by FDA is not required before the labeling is used.

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Carol Hill, Regulatory Project Manager, at (301) 796-1226.

Sincerely,

*{See appended electronic signature page}*

Badrul A. Chowdhury, M.D., Ph.D..
Director
Division of Pulmonary and Allergy Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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

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/s/
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Sally Seymour
12/28/2006 05:41:07 PM
for Badrul A. Chowdhury