DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-800/S-005

Hollister-Stier Laboratories LLC
3525 North Regal Street
Spokane, WA 99207-5796

Attention: David L. Mirabell
Director, Regulatory Affairs and Professional Services

Dear Mr. Mirabell:

Please refer to your supplemental new drug application dated October 21, 2004, received October 22, 2004, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Twinject Auto-Injector (epinephrine injection, USP 1:1000).

We acknowledge receipt of your submissions dated November 24, and December 6, 2004, and February 2, 2005.

This supplemental new drug application provides for a design modification and revisions to the 0.30 dose labeling to incorporate revisions approved in the supplemental application for the 0.15 mg dose.

We 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 and the revision listed below and agreed to in a telephone conversation on February 18, 2005.

1. Revise the trade name throughout the labeling to Twinject 0.30 mg.

2. The following statement should appear adjacent to the trade name through out the labeling:

   Each dose delivers 0.3 mg of epinephrine.

3. Revise bullet 3 in the section titled "How should I use Twinject 0.3 mg?" in the patient information leaflet to read as follows:

   If you are not able to give an injection because of arthritis, Twinject 0.3 ml may not be right for you.

4. Increase the prominence of the word "Demonstrator" and decrease the prominence of the trade name, Twinject 0.30 on the demonstrator labeling.

The final printed labeling (FPL) must be identical, and include the minor editorial revision indicated, to the labeling submitted on October 21, 2004. This revision is a term of the approval of this application.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, but no more than 30 days after it is printed. 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-005**." 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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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) 827-5584.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Director
Division of Pulmonary and Allergy Drug Products, HFD-570
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/

Badrul Chowdhury
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