DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-800/S-007

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 March 1, 2005, received March 2, 2005, 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 also acknowledge receipt of your submission dated May 3, and June 29, 2005.

This supplemental new drug application provides for design and manufacturing modifications and revisions to the 0.15 mg dose labeling to incorporate revisions approved in the supplemental application for the 0.3 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.

The final printed labeling (FPL) must be identical to the submitted labeling (text for package insert, carton and shipping carton labels submitted on June 29, 2005).

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-007**." Approval of this submission by FDA is not required before the labeling is used.

The following revisions should be made to the package insert at the next printing.

1. Insert a hyphen between the words ‘Two’ and ‘Pack’ in the HOW SUPPLIED section.

2. In paragraph three, line 5 of the DOSAGE and ADMINISTRATION section, change ‘pounds))’ to ‘pounds)’

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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