DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-859/S-002

Halozyme Therapeutics, Inc.
Attention: Don Kennard
Vice President Regulatory Affairs
11588 Sorrento Valley Road, #17
San Diego, CA 92121

Dear Mr. Kennard:

Please refer to your supplemental new drug application dated April 10, 2006, received April 12, 2006, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Hylenex (hyaluronidase human injection).

We acknowledge receipt of your submission dated June 1, 2006.

This supplemental new drug application proposes revisions to the Description and How Supplied sections of the labeling, and proposes to replace the ten vial carton with a four vial carton. Additionally, the 1 ml single dose will no longer be available in a box of one.

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on April 10, 2006 (package insert) and June 1, 2006 (unit carton and ten unit package carton.)

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

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

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Alison Rodgers, Regulatory Project Manager, at (301) 796-0797.

Sincerely,

{See appended electronic signature page}

Eric Duffy, Ph.D.
Director
Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
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/

Eric Duffy
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