CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-859

MICROBIOLOGY REVIEW

Product Quality Microbiology Review
Review for HFD-520

04 AUG 2005

NDA: **21-859**

Drug Product Name
Proprietary: Hylenex (was Enhanze SC)
Non-proprietary: recombinant human hyaluronidase
Drug Product Priority Classification: P

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Consult Sent	Assigned to Reviewer
18 MAR 2005	24 MAR 2005	28 MAR 2005	04 APR 2005

Submission History (for amendments only) N.A.

Applicant/Sponsor
Name: Halozyme Therapeutics, Inc.
Address: 11588 Sorrento Valley Road Suite 17
San Diego, CA 92121
Representative: Don Kennard, V.P. Quality
Telephone: 858 794-8889 ex 208

Name of Reviewer: James L. McVey

Conclusion: Recommend approval from a Product Quality Microbiology perspective.

Product Quality Microbiology Data Sheet

A. 1. **TYPE OF SUBMISSION:** New drug application, electronic

2. **SUBMISSION PROVIDES FOR:** Manufacturing and sale.

3. **MANUFACTURING SITE:** Manufacturing, testing and packaging will be done at: [ ]

Establishment Number —

4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** 150 USP Units in 1 mL. Injection (not IV)

5. **METHOD(S) OF STERILIZATION:** [ ]

6. **PHARMACOLOGICAL CATEGORY:** Used as an adjuvant.

B. **SUPPORTING/RELATED DOCUMENTS:** DMF [ ]

C. **REMARKS:** DMF — has a series of extensive annual updates rather than complete replacement. For this reason areas not covered are deemed acceptable based on prior reviews. At some point a complete DMF revision should be requested. A lot of the material needed is provided in the electronic document, which was reviewed first. The drug substance (provided sterile) and the human serum albumin (provided sterile) were not reviewed for sterility assurance since they are components of the finished drug product which is formulated under non sterile conditions. These components were reviewed for viral clearance.

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Executive Summary

I. Recommendations

A. Recommendation on Approvability - Approve

B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable - None

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology – The recombinant hyaluronidase is added to the compounded base solution last and the final volume is adjusted based on activity. The compounded bulk drug solution may be stored at 2 – 8 °C prior to

B. Brief Description of Microbiology Deficiencies - No deficiencies were noted.

C. Assessment of Risk Due to Microbiology Deficiencies – N.A.

III. Administrative

A. Reviewer's Signature _____

James L. McVey
Microbiology Reviewer

B. Endorsement Block

Brian Riley Ph.D.

C. CC Block

DFS

8 Page(s) Withheld

✓ § 552(b)(4) Trade Secret / Confidential

_____ § 552(b)(5) Deliberative Process

_____ § 552(b)(5) Draft Labeling

*Withheld Track Number: Microbiology-*1

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

/s/

James McVey
8/5/05 09:09:48 AM
MICROBIOLOGIST

Bryan Riley
8/5/05 09:40:05 AM
MICROBIOLOGIST