CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 21-075

MICROBIOLOGY REVIEW(S)

FINS

REVIEW FOR HFD-510
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #1 OF NDA

NOV 1 3 1999

November 2, 1999

A. 1. NDA 21-075

SPONSOR Genentech, Inc.
One DNA Way
South San Francisco, CA 94080

2. PRODUCT NAMES: [redacted] (Nutropin Depot [recombinant Human Growth Hormone])

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: A sterile powder for re-suspension in Diluent, packaged in a kit that includes one vial of Nutropin Depot (13.5 mg, 18 mg, or 22.5 mg dosage unit), one vial of Diluent for Nutropin Depot, three 21-gauge needles, and a patient and physician's insert.

4. METHOD(S) OF STERILIZATION: The Nutropin Depot is prepared by [redacted] The Diluent for Nutropin Depot is [redacted]

5. PHARMACOLOGICAL CATEGORY: Growth hormone, sustained release microspheres

6. DRUG PRIORITY CLASSIFICATION: 3P

B. 1. DATE OF INITIAL SUBMISSION: June 25, 1999

2. DATE OF AMENDMENT: (none)

3. RELATED DOCUMENTS: DMF [redacted], and IND [redacted] rHGH).

4. ASSIGNED FOR REVIEW: July 16, 1999

C. REMARKS: This NDA is based on IND [redacted] The NDA describes the manufacture of a recombinant protein drug substance by Genentech through its processing into a microspheres, and [redacted] processing as a powder for suspension in a diluent for injection. The submission refers to DMF [redacted] for the manufacture of the diluent packaged with the microspheres. The [redacted] DMF refers to DMF [redacted] for the information specific to the facilites used to

manufacture of the diluent (in vials) that is packaged as part of this finished product.

D. CONCLUSIONS: The application is recommended for APPROVAL.

/S/ 11-2-99
David Hussong, Ph.D.

/S/ 11/3/99

cc:

HFD 160/Consult File
HFD 510/CSO/C. King
HFD 510/Chemist
HFD 805/D. Hussong

Drafted by: D. Hussong, 11/02/99
R/D initialed by: P. Cooney

APPEARS THIS WAY
ON ORIGINAL