CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-484

MICROBIOLOGY REVIEW

OLIVER

SEP - 3 1999

REVIEW FOR HFD-180
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #1 OF NDA 20-484
1 September 1999

A. 1. NDA 20-484

APPLICANT: DuPont Life Sciences Enterprise
Dupont Pharmaceuticals Company
Chestnut Run Plaza
Centre Road
Wilmington, DE 19805

2. PRODUCT NAMES: Innohep® (tinzaparin sodium injection)

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
The product is intended only for subcutaneous injection.

4. METHODS OF STERILIZATION:
The drug product is [redacted]

5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:
The drug product is indicated for the initial treatment of acute symptomatic deep vein thrombosis with and without pulmonary embolism when administered in conjunction with warfarin sodium.

B. 1. DATE OF INITIAL SUBMISSION: 30 June 1999

2. DATE OF AMENDMENT: (none)

3. RELATED DOCUMENTS: [redacted]

4. ASSIGNED FOR REVIEW: 27 July 1999

C. REMARKS: The application provides for a two product strengths, 10,000 anti-Xa per mL and 20,000 anti-Xa per mL both packaged in 2 mL multi-use vials. The product is preserved with benzyl alcohol.

The product will be manufactured by [redacted].

D. CONCLUSIONS: The application is recommended for approval on the basis of sterility assurance.

/S/

1 September 1999

Paul Stinavagé, Ph.D.

/S/ 9/3/99

cc: Original NDA 20-484
HFD-805/Stinavage/Consult File
HFD-180/Div File/K. Oliver/A. Al-Hakim

Drafted by: P. Stinavage, 1 September 1999
R/D initialed by P. Cooney