CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER
21-172

Microbiology Review(s)

APR 20 2000

REVIEW FOR HFD-510
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW OF NDA 21-172
18 April 2000

A. 1. NDA 21-172
APPLICANT: Novo Nordisk Pharmaceuticals, Inc.
Suite 200
100 Overlook Center
Princeton, NJ 08540-7810

2. PRODUCT NAME: Biphasic Insulin Aspart 30 ([redacted] 70/30 injection)

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
The product is a sterile injectable preparation for subcutaneous injection.

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

5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:
The drug product is indicated in the treatment of diabetes mellitus.

B. 1. DATE OF INITIAL SUBMISSION: 22 December 1999

2. DATE OF AMENDMENT: 4 January 2000 (Subject of this Review.)

3. RELATED DOCUMENTS: IND [redacted] NDA 19-938; NDA 20-986

4. ASSIGNED FOR REVIEW: 10 January 2000

C. REMARKS: The product will be manufactured by:

Novo Nordisk A/S
Novo Alle
DK-2880 Bagsvaerd
Denmark

The applicant is seeking approval for the following packaging presentations:

Biphasic Insulin Aspart 30 – 10 mL Vial
Biphasic Insulin Aspart 30 PenFill® 3 mL cartridge
Biphasic Insulin Aspart 30 Prefilled® Syringe
([redacted] 3 mL)

The Syringe presentation uses the identical cartridges as the PenFill® presentation.

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

/S/ 18 April 2000
Paul Stinavage, Ph.D.
/S/ 4/20/00

cc: Original NDA 21-172
HFD-510/J. Rhee/Div. File
HFD-805/Consult File/Stinavage

Drafted by: P. Stinavage, 18 April 2000
R/D initialed by P. Cooney

APPEARS THIS WAY
ON ORIGINAL