

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPROVAL PACKAGE FOR:**

**APPLICATION NUMBER**

**21-172**

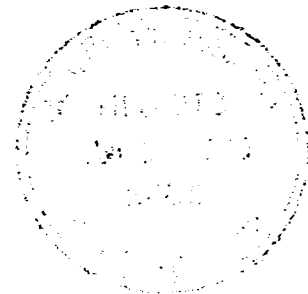
**Microbiology Review(s)**

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 (  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
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  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  
( 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.

*IS/IS/*  
~~Paul Stinavage, Ph.D.~~ *18 April 2000*  
*3/20/00*

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**