

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-148

MICROBIOLOGY REVIEW

510/Keny

APR 19 2000

REVIEW FOR HFD-510

**OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF HFD-805
Microbiologist's Review #2 of NDA 21-148**

April 19, 2000

- A. 1. APPLICATION NUMBER:** 21-148
- APPLICANT:** Novo Nordisk Pharmaceuticals
100 Overlook Center Suite 200
Princeton, NJ 08540-7810
Phone (609) 987-5877
FAX (609) 987-3916
- 2. PRODUCT NAME:** Norditropin® SimpleXx™ Cartridges
- 3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:** Somatropin (rDNA origin) in 5, 10, and 15 mg cartridges for subcutaneous injection.
- 4. METHODS OF STERILIZATION:** _____
- 5. PHARMALOGICAL CATAGORY and/or PRINCIPLE INDICATION:** indicated for long-term treatment of children who have growth failure due to inadequate secretion of endogenous growth hormone.
- 6. DRUG PRIORITY CLASSIFICATION:** S
- B. 1. DATE OF INITIAL SUBMISSION:** June 30, 1999
- 2. DATE OF AMENDMENT:** April 3, 2000
- 3. DATE OF CONSULT:** April 3, 2000
- 4. ASSIGNED FOR REVIEW:** April 3, 2000
- 5. RELATED DOCUMENTS:** NDA 19-721

C. REMARKS:

The NDA was submitted to support a new dosage form of Somatropin. The drug product is currently marketed under NDA 19-721 as lyophilized Norditropin® (4 mg and 8 mg) in vials.

Microbiologist's Review #1 (dated 3/9/00) yielded deficiencies which were faxed to the applicant on 3/27/00. The applicant's 4/3/00 response to these deficiencies is the subject of this review (Microbiologist's Review #2).

D. CONCLUSIONS:

The submission is recommended for approval for microbiology issues concerning sterility assurance. Comments are provided in section "E. REVIEW NOTES".

BS

Neal Sweeney, Ph.D.

BS

cc: NDA 21-148
HFD-510/Division File
HFD-510/C. King
HFD-805/Consult File/N. Sweeney

Drafted by: N. Sweeney, April 19, 2000
R/D initialed by P. Cooney, April 19, 2000

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REVIEW FOR HFD-510
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF HFD-805
Microbiologist's Review #1 of NDA 21-148

March 9, 2000

- A. 1. APPLICATION NUMBER: 21-148
- APPLICANT: Novo Nordisk Pharmaceuticals
100 Overlook Center Suite 200
Princeton, NJ 08540-7810
Phone (609) 987-5877
FAX (609) 987-3916
- 2. PRODUCT NAME: Norditropin® SimpleXx™ Cartridges
- 3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Somatropin (rDNA origin) in 5, 10, and 15 mg cartridges for subcutaneous injection.
- 4. METHODS OF STERILIZATION: _____
- 5. PHARMALOGICAL CATAGORY and/or PRINCIPLE INDICATION: indicated for long-term treatment of children who have growth failure due to inadequate secretion of endogenous growth hormone.
- 6. DRUG PRIORITY CLASSIFICATION: S
- B. 1. DATE OF INITIAL SUBMISSION: June 30, 1999
- 2. DATE OF CONSULT: July 15, 1999
- 3. ASSIGNED FOR REVIEW: Assigned to P. Hughes: July 21, 1999
Reassigned to N. Sweeney: October 28, 1999
- 4. RELATED DOCUMENTS: NDA 19-721
- C. REMARKS: The NDA was submitted to support a new dosage form of Somatropin. The drug product is currently marketed under NDA 19-721 as lyophilized Norditropin® (4 mg and 8 mg) in vials.

D. CONCLUSIONS:

The submission is approvable pending resolution of microbiology issues concerning sterility assurance. Specific comments and deficiencies are provided in section "E. REVIEW NOTES" and "List of Microbiology Deficiencies and Comments".

BS

Neal Sweeney, Ph.D.
BS

cc: NDA 21-148
HFD-510/Division File
HFD-510/C. King
HFD-805/Consult File/N. Sweeney

Drafted by: N. Sweeney, March 9, 2000
R/D initialed by P. Cooney, March 9, 2000

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