CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 21-081

MICROBIOLOGY REVIEW(S)

· 21 1999 New file

REVIEW FOR HFD-180
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #2 OF NDA 21-081
19 January 2000

A. 1. NDA 21-081
APPLICANT: Quintiles, Inc.
U.S. Agent for Hoechst Marion Roussel, Inc.
Post Office Box 9708
Kansas City, MO 64134-0708

2. PRODUCT NAMES: Lantus® (insulin glargine injection (rDNA origin))

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
The product is intended only for subcutaneous injection. Strength is 100 U/mL (U-100). The product is to be packaged in 5 and 10 mL vials as well as 3 mL cartridges.

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

5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:
The drug product is used to control blood glucose levels in the treatment of diabetes mellitus.

B. 1. DATE OF INITIAL SUBMISSION: 9 April 1999

2. DATE OF AMENDMENT: 22 November 1999 (Subject of this review)

3. RELATED DOCUMENTS: DMF's [redacted]
[redacted] IND [redacted]

4. ASSIGNED FOR REVIEW: 17 December 1999

C. REMARKS: The application provides for the marketing of a new insulin analogue. The product is to be manufactured at:
Hoechst Marion Roussel – Germany
Building H600

D-65926 Frankfurt am Main
Germany

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

/S/ 19 January 2000
Paul Stinavage, Ph.D.
/S/ 1/21/00

cc: Original NDA 21-081
HFD-805/Stinavage/Consult File
HFD-510/Div File/J. Rhee

Drafted by: P. Stinavage, 19 January 2000
R/D initialed by P. Cooney

APPEARS THIS WAY
ON ORIGINAL

OCT - 6 1999

REVIEW FOR HFD-180
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #1 OF NDA 21-081
6 October 1999

A. 1. NDA 21-081
APPLICANT: Quintiles, Inc.
U.S. Agent for Hoechst Marion Roussel, Inc.
Post Office Box 9708
Kansas City, MO 64134-0708

2. PRODUCT NAMES: Lantus® (insulin glargine injection (rDNA origin))

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
The product is intended only for subcutaneous injection. Strength is 100 U/mL (U-100). The product is to be packaged in 5 and 10 mL vials as well as 3 mL cartridges.

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

5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:
The drug product is used to control blood glucose levels in the treatment of diabetes mellitus.

B. 1. DATE OF INITIAL SUBMISSION: 9 April 1999

2. DATE OF AMENDMENT: 2 September 1999 (included in this review)

3. RELATED DOCUMENTS: DMF's [redacted]
[redacted] IND [redacted]

4. ASSIGNED FOR REVIEW: 14 May 1999

C. REMARKS: The application provides for the marketing of a new insulin analogue. The product is to be manufactured at:
Hoechst Marion Roussel – Germany
Building H600

D-65926 Frankfurt am Main
Germany

D. CONCLUSIONS: The application is approvable pending resolution of microbiology concerns.

/S/ 6 October 1999
Paul Stinavage, Ph.D.

cc: Original NDA 21-081
HFD-805/Stinavage/Consult File
HFD-510/Div File/J. Rhee

Drafted by: P. Stinavage, 6 October 1999
R/D initialed by P. Cooney /S/ for PStC 10-6-99

APPEARS THIS WAY
ON ORIGINAL