CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 21-017
21-018

MICROBIOLOGY REVIEW(S)

Comments faxed to the sponsor 2-3-99

/S/

JAN 29 1999

REVIEW TO HFD-510
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST REVIEW OF A NDA
January 21, 1999

A. NDA 21-017

PRODUCT NAME: Humalog® Mix25™
25% Insulin Lispro Injection and 75% Insulin Lispro Protamine Suspension (rDNA origin)

APPLICANT: Eli Lilly and Company
Lilly Corporate Center
Indianapolis, IN 46285

DOSAGE FORM: Injectable, 100 Units/mL for Subcutaneous administration
METHOD OF STERILIZATION: [redacted]
PHARMACOLOGICAL CATEGORY: Treatment of hyperglycemia

B. INITIAL APPLICATION DATE: December 21, 1998
ASSIGNED FOR REVIEW: January 4, 1999

C. REMARKS: This NDA which provides for Humalog®Mix25™ in 10 mL vials and in 3.0 mL cartridges is the same as NDA 21-018 which provides for Humalog®Mix50™, except for items 2 (Labeling), 3 (Application Summary) and 4 (Chemistry Section). Product quality microbiology CMC information is included under item 7 and is the same in both NDAs.

D. CONCLUSIONS: The NDA 21-017 for Humalog®Mix25™ is approvable pending resolution of product quality microbiology issues.

/S/ 1/21/99
Patricia F. Hughes, Ph. D.
Review Microbiologist

/S/ 1/29/99

cc.: Original NDA 21-017
HFD-160 /Consult File
HFD-805/PFHughes
HFD-510/JRhee
HFD-510/Division File
Drafted by PFHughes/January 21, 1999
R/D Initialed by PHCooney

Comments faxed to the sponsor 2-3-99 /S/

JAN 29 1999

REVIEW TO HFD-510
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST REVIEW OF A NDA
January 21, 1999

A. NDA 21-018

PRODUCT NAME: Humalog® Mix50™
50% Insulin Lispro Injection and 50% Insulin Lispro Protamine Suspension (rDNA origin)

APPLICANT: Eli Lilly and Company
Lilly Corporate Center
Indianapolis, IN 46285

DOSAGE FORM: Injectable, 100 Units/mL for Subcutaneous administration
METHOD OF STERILIZATION: [redacted]
PHARMACOLOGICAL CATEGORY: Treatment of hyperglycemia

B. INITIAL APPLICATION DATE: December 21, 1998
ASSIGNED FOR REVIEW: January 4, 1999

C. REMARKS: This NDA which provides for Humalog®Mix50™ in 10 mL vials and in 3.0 mL cartridges is the same as NDA 21-017 which provides for Humalog®Mix25™, except for items 2 (Labeling), 3 (Application Summary) and 4 (Chemistry Section). Product quality microbiology CMC information is included under item 7 and is the same in both NDAs.

D. CONCLUSIONS: The NDA 21-018 for Humalog®Mix50™ is approvable pending resolution of product quality microbiology issues.

/S/ 1/21/99
Patricia F. Hughes, Ph. D.
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/S/

APR 1 2 1999

REVIEW TO HFD-510
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST REVIEW OF AN AMENDMENT
9 April 1999

A. NDA 21-017

PRODUCT NAME: Humalog® Mix25™
25% Insulin Lispro Injection and 75% Insulin Lispro Protamine Suspension (rDNA origin)

APPLICANT: Eli Lilly and Company
Lilly Corporate Center
Indianapolis, IN 46285

DOSAGE FORM: Injectable, 100 Units/mL for Subcutaneous administration
METHOD OF STERILIZATION: [redacted]
PHARMACOLOGICAL CATEGORY: Treatment of hyperglycemia

B. INITIAL APPLICATION DATE: 21 December 1998
DATE OF AMENDMENT # 1: 17 February 1999
ASSIGNED FOR REVIEW: 1 March 1999

C. REMARKS: The amendment dated February 17, 1999 contains responses to microbiology deficiencies found in the original application.

D. CONCLUSIONS: The NDA 21-017 for Humalog®Mix25™ is recommended for approval from the standpoint of product quality microbiology.

/S/ 9 Apr 1999

Patricia F. Hughes, Ph. D.
Review Microbiologist

/S/ 4/12/99

cc.: Original NDA 21-017
HFD-160 /Consult File
HFD-805/PFHughes
HFD-510/JRhee
HFD-510/Division File
Drafted by PFHughes/9 April 1999
F/D Initialed by PHCooney

/S/

REVIEW TO HFD-510
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST REVIEW OF AN AMENDMENT
9 April 1999

APR 1 2 1999

A. NDA 21-018

PRODUCT NAME: Humalog® Mix50™
50% Insulin Lispro Injection and 50% Insulin Lispro Protamine Suspension (rDNA origin)

APPLICANT: Eli Lilly and Company
Lilly Corporate Center
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DOSAGE FORM: Injectable, 100 Units/mL for Subcutaneous administration
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/S/ 9/Apr/1999

Patricia F. Hughes, Ph. D.
Review Microbiologist

/S/ 4/12/99

cc.: Original NDA 21-018
HFD-160 /Consult File
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R/D Initialed by PHCooney

APPEARS THIS WAY
ON ORIGINAL