CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 21-017
21-018

MICROBIOLOGY REVIEW(S)
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: 
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.

Patricia F. Hughes, Ph. D.
Review Microbiologist

cc: Original NDA 21-012
HFD-160/Consult File
HFD-805/PH Hughes
HFD-510/JRhee
HFD-510/Division File
Drafted by PF Hughes/January 21, 1999
R/D Initiated by PH Cooney

/Seal/ 2/19/99
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: __________________
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.

Patricia F. Hughes, Ph. D.
Review Microbiologist

cc.: Original NDA 21-018
HFD-160 /Consult File
HFD-805/PHHughes
HFD-510/Rhee
HFD-510/Division File
Drafted by PHHughes/January 21, 1999
R/D Initiated by PHHughes
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: Treatment of hyperglycemia

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.

Patricia F. Hughes, Ph. D.
Review Microbiologist

cc: Original NDA 21-017
HFD-160 Consult File
HFD-805/PFHughes
HFD-510/JRhee
HFD-510/Division File
Drafted by PF Hughes/9 April 1999
R/D Initiated by PH Cooney
REVIEW TO HFD-510
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST REVIEW OF AN AMENDMENT
9 April 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: }

PHARMACOLOGICAL CATEGORY: Treatment of hyperglycemia

B. INITIAL APPLICATION DATE: 21 December 1998
DATE OF AMENDMENT # 1: 17 February 1999
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C. REMARKS: The amendment dated February 17, 1999 contains responses to
microbiology deficiencies found in the original application.

D. CONCLUSIONS: The NDA 21-018 for Humalog®Mix50™ is recommended for
approval from the standpoint of product quality microbiology.

Patricia F. Hughes, Ph. D.
Review Microbiologist

APPEARS THIS WAY ON ORIGINAL