CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 75-241

BIOEQUIVALENCE REVIEW(S)

Furosemide Injection
10 mg/ml in plastic syringe
NDA #75-241
Reviewer: J. Lee
75241W.O97

Abbott Laboratories
Abbott Park, Illinois
Submission date:
October 31, 1997

Review of a Request for Waiver

The sponsor has submitted an application for furosemide injection in 10 mg/ml plastic syringes and is requesting a waiver of in-vivo bioavailability test requirements per 21 CFR 320.22 (b)(1).

The drug product is a diuretic intended for IV or IM administration.

Presented below is a formulation comparison of the test/reference products:

	Abbottt per ml	Lasix® per ml
Furosemide	10 mg	10 mg
NaCl	7.5 mg	adj. tonicity*
NaOH	- - -	adj. pH
HCl/NaOH	adj. pH	- - -
Water for Injection	q.s.	q.s.

* Agency records have previously indicated that Lasix® injection contained _ of NaCl; however, present database records and Lasix® labeling now refer to the amount of NaCl in the formulation as 'adjust tonicity'.

Comment:

1. Abbott's formulation meets the requirements of OGD's Inactive Ingredients Guideline.

Recommendation:

1. The Division of Bioequivalence finds that the information submitted by Abbott Laboratories demonstrates that furosemide injection 10 mg/ml in plastic syringes falls under 21 CFR 320.22 (b)(1) of Bioavailability/Bioequivalence Regulations. The Division of Bioequivalence recommends that the waiver of an in-vivo bioavailability study be granted. Abbott's test product is deemed bioequivalent to Lasix® injection 10 mg/ml manufactured by Hoechst Marion Roussel.

R. Lee 2/17/98
J. Lee

Division of Bioequivalence
Review Branch II

/S/ 2/17/1998

RD INITIALED SNERURKAR
FT INITIALED SNERURKAR

Concur: /S/ Date: 2/18/98

Dale Conner, Pharm. D.
Director, Division of Bioequivalence

JLee/jl/02-17-98

c

BIOEQUIVALENCY COMMENTS TO BE PROVIDED TO THE APPLICANT

ANDA:75-241 APPLICANT: Abbott Laboratories

DRUG PRODUCT: Furosemide injection 10 mg/ml in plastic syringes

The Division of Bioequivalence has completed its review and has no further questions at this time.

Please note that the bioequivalency comments provided in this communication are preliminary. These comments are subject to revision after review of the entire application, upon consideration of the chemistry, manufacturing and controls, microbiology, labeling, or other scientific or regulatory issues. Please be advised that these reviews may result in the need for additional bioequivalency information and/or studies, or may result in a conclusion that the proposed formulation is not approvable.

Sincerely yours,

/S/

Dale P. Conner, Pharm.D.
Director Division of Bioequivalence
Office of Generic Drugs
Center for Drug Evaluation and Research