

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 20822

CHEMISTRY REVIEW(S)

APR 23 1998

DIVISION OF NEUROPHARMACOLOGICAL DRUG PRODUCTS
Review of Chemistry, Manufacturing, and Controls

NDA #: 20-822

CHEM.REVIEW # 2

REVIEW DATE: 22-APR-98

SUBMISSION TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
Amendment	02-APR-98	03-APR-98	07-APR-98
Amendment	15-APR-98	16-APR-98	16-APR-98

NAME & ADDRESS OF APPLICANT:

Forest Laboratories
 909 Third Avenue
 New York, N.Y. 10022-4731

DRUG PRODUCT NAME

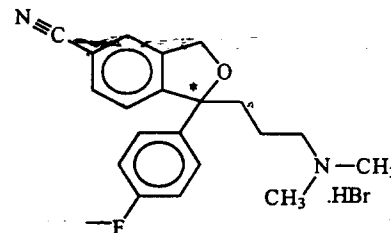
Proprietary:	Celex
Nonproprietary/USAN:	Citalopram Hydrobromide [non-USAN]
Code Name/#:	H Lu-171
Chem.Type/Ther.Class:	Antidepressant
PHARMACOL.CATEGORY/INDICATION:	Treatment of Depression
DOSAGE FORM:	Tablets
STRENGTHS:	10 mg, 20 mg, 40 mg & 60 mg
ROUTE OF ADMINISTRATION:	Oral
DISPENSED:	XXXXX Rx _____ OTC

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:

Name given by inventor [Lundbeck]: (+/-)-1-(3-dimethylaminopropyl)-1-(4-fluorophenyl)-1,3-dihydroisobenzofuran-5-carbonitrile HBr
 1996 USAN published non-USAN name for free base: 1-[3-(Dimethylamino)-propyl]-1-(p-fluorophenyl)-5-phthalanecarbonitrile
 $C_{20}H_{21}FN_2O.HBr$; Molecular Weight: 405.35;
 CAS #: 59729-32-7 (Racemate)

SUPPORTING DOCUMENTS:

RELATED DOCUMENTS: None



CONCLUSIONS & RECOMMENDATIONS: Recommend approval of NDA 20-822, as amended, with 24 months expiration dating period. The sponsor should: 1) acquire an USAN name for the drug substance,

cc: Orig. NDA 20-822
 HFD-120
 HFD-120/WJRzeszotarski
 HFD-120/PDavid
 HFD-120/MEGuzewska
 HFD-810/JSimmons
 R/D Init by:MEG /S/ 23.98

/S/
 W. Janusz Rzeszotarski, Ph.D., Chemist

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DIVISION OF NEUROPHARMACOLOGICAL DRUG PRODUCTS
Review of Chemistry, Manufacturing, and Controls

NDA #: 20-822

CHEM.REVIEW # 1

FEB 12 1998

REVIEW DATE: 24-DEC-97
(05-FEB-98)

SUBMISSION TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
ORIGINAL	07-MAY-97	12-MAY-97	20-MAY-97
Amendment	15-JUL-97	16-JUL-97	16-JUL-97
Amendment	30-JUL-97	31-JUL-97	31-JUL-97
Amendment	28-AUG-97	02-SEP-97	02-SEP-97
Amendment	28-OCT-97	31-OCT-97	31-OCT-97
Amendment	18-NOV-97	01-DEC-97	01-DEC-97
Amendment	18-DEC-97	19-DEC-97	19-DEC-97
Amendment	16-JAN-98	19-JAN-98	19-JAN-98

NAME & ADDRESS OF APPLICANT:

Forest Laboratories
909 Third Avenue
New York, N.Y. 10022-4731

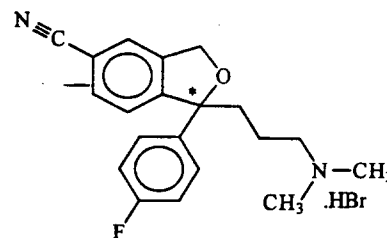
DRUG PRODUCT NAME

Proprietary: Sertin
Nonproprietary/USAN: Citalopram Hydrobromide
Code Name/#: H Lu-171
Chem.Type/Ther.Class: Antidepressant
PHARMACOL.CATEGORY/INDICATION: Treatment of Depression
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STRENGTHS: 10 mg, 20 mg, 40 mg & 60 mg
ROUTE OF ADMINISTRATION: Oral
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(+/-)-1-(3-dimethylaminopropyl)-1-(4-fluorophenyl)-1,3-dihydroisobenzofuran-5-carbonitrile HBr

C₂₀H₂₁FN₂O.HBr; Molecular Weight: 405.35;
CAS #: 59729-32-7 (Racemate)
SUPPORTING DOCUMENTS:
RELATED DOCUMENTS: None



CONCLUSIONS & RECOMMENDATIONS: Recommend NDA 20-822 APPROVABLE, subject to an acceptable EER for the uninspected facilities and the resolution of the bioequivalency issue, with the 18 months expiration date.

cc: Orig. NDA 20-822

HFD-120

HFD-120/WJRzeszotarski

HFD-120/PDavid

HFD-120/MEGuzewska

HFD-810/JSimons

R/D Init by:MEG

W. Janusz Rzeszotarski, Ph.D., Chemist

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