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Application Number 21-865

PHARMACOLOGY REVIEW(S)

Pharmacology/Toxicology Review of New Drug Application

NDA:	21-365
Sponsor:	Forest Laboratories, Inc.
Drug	Lexapro (escitalopram oxalate) Oral Solution
Indication:	
Letter Dates:	November 2, 2001
Reviewer:	Paul Roney
Review Date	May 23, 2002

The sponsor has submitted a New Drug Application for the oral solution of Lexapro (escitalopram) for the treatment of major depressive disorder. The sponsor did not submit any additional nonclinical pharmacology or toxicology studies. Instead the sponsor cross-referenced the data from NDA 21-363 for escitalopram tablets. The pharmacology and toxicology data in NDA 21-323 were reviewed on December 3, 2001 and May 23, 2002 and found adequate to support the application. The division issued an approvable letter NDA 21-323 on January 23, 2002 and is currently reviewing the sponsor's response to the approvable letter. Since no inactive ingredients of concern were identified in the product description, there are adequate pharmacology and toxicology studies to support the approval of this drug product.

This NDA is approvable with respect to the pharmacology/toxicology portion pending labeling revision (see labeling recommendations made in NDA 21-323).

Reviewer signature/team leader signature [Concurrence/Non-concurrence]

Paul L. Roney, Ph.D.

APPEARS THIS WAY
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/s/

Paul Roney
5/23/02 03:28:47 PM
PHARMACOLOGIST

Barry Rosloff
8/23/02 04:26:11 PM
PHARMACOLOGIST

APPEARS THIS WAY
ON ORIGINAL

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