CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-802

PHARMACOLOGY REVIEW

May 10, 2005

Review and Evaluation of Pharmacology and Toxicology
Original NDA Review

NDA: 21-802

Sponsor: Novartis
East Hanover, NJ

Received: July 28, 2004

Drug: Dexmethylphenidate hydrochloride (Focalin) extended-release capsules

Indication: ADHD

Recommendations:

This application for an extended-release dosage form of dexmethylphenidate relies on preclinical toxicology data submitted to the original tablet NDA (21-278) for supporting safety information. This is considered adequate for the drug substance; and since there are no new impurities or unusual excipients in the new formulation, there are no Pharm/Tox objections to approval.

cc:
NDA (21-802)
Div File
HFD-120/LFreed/RTaylor/EFisher

J.E. Fisher, Ph.D.

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/s/

Edward Fisher
5/11/05 03:31:37 PM
PHARMACOLOGIST

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