CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

83-564

APPROVAL LETTER

NDA 83-564
AF 9-389

OCT 24 1975

Delco Chemical Company, Inc.
Attention: Louis Cohen
7 MacQuesten Parkway North
Mount Vernon, NY 10550

Gentlemen:

Reference is made to your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Delcobese Capsules, 5 mg., 10 mg., 15 mg., and 20 mg.

Reference is also made to your communications dated October 20 and 24, 1975.

We have completed the review of this abbreviated new drug application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved.

Any significant change in the conditions outlined in this abbreviated new drug application requires an approved supplemental application before the change may be made, except for changes made in conformance with other provisions of Section 314.8 of the new drug regulations.

This Administration should be advised of any change in the marketing status of this drug.

Promotion of a product marketed under an abbreviated new drug application must not convey the impression that the product is a new entity.

The enclosures summarize the conditions relating to the approval of this application.

Sincerely yours,

Marvin Seife 10/24/75

Marvin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

HYC-DD