

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

83-564

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW FOR
ABREVIATED NEW DRUG APPLICATION
OR SUPPLEMENT

Federal Register
Statement Date

ANDA Number 83-563

9-389

AF Number

Name and Address of Applicant (City and State)
Delco Chemical Company, Inc.
Mount Vernon, NY 10550

Original _____
Amendment xxxxx
Supplement _____
Resubmission _____
Correspondance _____
Report _____
Other _____

Purpose of Amendment/Supplement
modified specifications/tests

Date(s) of Submission(s)
10-20-75
10-24-75

Pharmacological Category
amphetamine

Name of Drug
Delcobese

Dosage Form(s)
tablets

Potency (ies)
5 mg, 10 mg., 15 mg., 20 mg.

How Dispensed
Rx xxxxx
OTC

Packaging/Sterilization

Samples

Related IND/NDAs/NFs
83-563 tablets
83-564 capsules

Labeling
satisfactory per medical officer's review of 10-23-75.

Biologic Availability
not required

Establishment Inspection
satisfactory for inwood ~~per~~ HFD-322 related memo of 10-21-74

Components, Composition, Manufacturing and Controls
satisfactory

Remarks
approval majarski

Majarski 10/24/75

Conclusion

REVIEWED DATE

REVIEW OF RESUBMISSION

DATE COMPLETED: 10-23-73

ANDA #: 83-564

F.R. DATE: 2-12-73

CO. NAME: Delco Chemical Co., Inc.
7 MacQueston Parkway N.
Mt. Vernon, NY 10550

NAME OF DRUG: Trade: Delcobese Capsules, 5 mg., 10 mg., 15 mg., 20 mg.
Generic: Amphetamines

DATE OF SUBMISSION: 8-15-73 Received for review 10-23-73

TYPE OF SUBMISSION: Resubmission

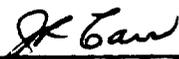
CLINICAL EVALUATION:

1. Review of Studies: For review by the chemist.
2. Review of Labeling:
 - a) Container labels: Satisfactory
 - b) Package insert: Revise in accord with labeling guidelines including the box warning at the beginning of the insert. Again, we are requesting that the promotional material at the top of the insert listed as "Supplied In" must be labeled How Supplied and placed in the proper format as stated in CFR 3.74 i.e. at the end of the insert.

CONCLUSION:

1. The container labels are acceptable.
2. The package insert must be revised as noted above before approval can be granted.

RECOMMENDATIONS: The company is to be so notified.



J.R. Carr, D.D.S.

CHEMIST'S REVIEW FOR ABREVATED NEW DRUG APPLICATION OR SUPPLEMENT		Federal Register Statement Date	ANDA Number 83-564
Name and Address of Applicant (City and State) Delco Chemical Company, Inc. Mount Vernon, NY 10550		AF Number	
Purpose of Amendment/Supplement updating of Inwood SDP stability data for capsules - product carries a 3 yr. expiration date		Date(s) of Submission(s) 11-14-75	
Pharmacological Category amphetamine	Name of Drug delcobese	How Dispensed Rx xxxxx OTC	
Dosage Form(s) capsule	Potency (ies) see PI sheet	Related IND/INDA/ME 83-563 tablets 83-564 capsules	
Packaging/Sterilization	Samples		
Labeling			
Biologic Availability			
Establishment Inspection			
Components, Composition, Manufacturing and Controls			
Remarks Note: all enclosures in 83-563 approval majarski			
Conclusion <i>Majarski 12/18/75</i>			
REVIEWER		DATE	