

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
85035

MEDICAL REVIEW

REVIEW OF RESUBMISSION

DATE COMPLETED: 6-22-77

ANDA #: 85-035

CO. NAME: Generics Pharmaceutical Corp
Palisades Park, NJ 07650

NAME OF DRUG: Diphenoxylate HCl + Atropine Sulfate Tablets
2.5 mg. 0.25 mg.

DATE OF SUBMISSION: 5-27-77

TYPE OF SUBMISSION: RESUBMISSION - reply to FDA letter 2-22-77

CLINICAL EVALUATION:

1. Review of Studies:

Pertinent data is to be reviewed by the chemist.
Bio requirement - not required.

2. Review of Labeling:

- a) Container labels: satisfactory CV
Diphenoxylate 2.5 mg. bottles of 500, 1000
w/Atropine Sulfate

"J-Davis"

- b) Insert labeling: Satisfactory (MOR 12-6-75)
date: 9-76

CONCLUSION: labeling is satisfactory

RECOMMENDATIONS: The firm is to be so notified.

/S/
Y.V. Karusaitis, M.D.

cc:dup
VVK/wlb/6-22-77

NOTICE OF APPROVAL
NEW DRUG APPLICATION OR SUPPLEMENT

NDA NUMBER

35-135

DATE APPROVAL LETTER ISSUED

TO:

Press Relations Staff (HFI-40)

FROM:

Bureau of Drugs

Bureau of Veterinary Medicine

ATTENTION

Forward original of this form for public information after approval letter has been issued and the date of approval has been entered above.

ORIGINAL ABBREVIATED

TYPE OF APPLICATION

ORIGINAL NDA

SUPPLEMENT TO NDA

ABBREVIATED ORIGINAL NDA

SUPPLEMENT TO ANDA

CATEGORY

HUMAN

VETERINARY

TRADE NAME (or other designated name) AND ESTABLISHED OR NONPROPRIETARY NAME (if any) OF DRUG

diphenoxylate HCl + atropine sulphate

DOSAGE FORM

oral

HOW DISPENSED

RX

OTC

ACTIVE INGREDIENT(S) (as declared on label. List by established or nonproprietary name(s) and include amount(s), if amount is declared on label.)

diphenoxylate HCl +
atropine SO₄
2.5/0.025 mgs

NAME OF APPLICANT (Include City and State)

Generic Pharmaceutical Corp.
Palisades Park, NJ 07650

PRINCIPAL INDICATION OR PHARMACOLOGICAL CATEGORY

antiperistaltic

COMPLETE FOR VETERINARY ONLY

ANIMAL SPECIES FOR WHICH APPROVED

COMPLETE FOR SUPPLEMENT ONLY

CHANGE APPROVED TO PROVIDE FOR

FORM PREPARED BY

NAME

quillar

DATE

FORM APPROVED BY

NAME

jlreyer

DATE

REVIEW OF AMENDMENT, RESUBMISSION, FPL

DATE COMPLETED: 11-30-76

ANDA #: 85-035

CO. NAME: Generic Pharm. Corp.
Palisades Park, NJ 07650

NAME OF DRUG: Diphenoxylate 0.25 mg. (with atropine sulfate 0.25 mg.) Tablets

DATE OF SUBMISSION: 11-12-76

TYPE OF SUBMISSION: Amendment, FPL

CLINICAL EVALUATION:

Pertinent material is to be reviewed by the chemist. Comparative dissolution study: "Lomotil" versus Generic Product.

1. Review of Labeling:

- a) Container labels: Satisfactory CV
2.5 mg. tablets bottles of 500, 1,000
- b) Insert labeling: Satisfactory
Date: 9-76

QUESTION: Propriety of Pharmacist warning to Patient???

RECOMMEND: Deletion of reference to pharmacist.

CONCLUSION: Insert labeling is satisfactory for the safe and effective use of this product. Question of propriety of Pharmacist warning to patient.

RECOMMENDATIONS: The firm is to be so notified.

/S/

(V.V. Karusaitis, M.D.

cc:
Dup
VVK/wlb/12-6-76