CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

85035

<u>APPROVAL LETTER</u>

NDA 85-035

Generic Pharmaceutical Corp.
Attention: Mr. Bernard Abramson
433 Commercial Avenue
Palisades Park, NJ 07650

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 Diphenoxylate HCl & Atropine Sulfate Tablets, (2.5 mg. & 0.025 mg.
respectively).

We acknowledge receipt of your communication dated May 27, 1977, amending
the application.

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.

The requirement for adequate data to assure the biologic availability
is being deferred at the present time. However, our action in approving
this application is based upon an understanding that if this requirement
is reinstated you will perform the appropriate procedures.

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.

NDA Dup   S/Meyer 7/1/77   Sincerely yours,
HFD-614 HFD-616
VVKarusaitis/JMeyer/GMillar 6-29-77
rd/ init. JMeyer/MSeife 6-30-77   /Marvin Seife, M.D.
f/t/wlb/6-30-77   Director
approved.   Division of Generic Drug Monographs
                                       Office of Drug Monographs
                                       Bureau of Drugs

Enclosures:
  Conditions of Approval of a New Drug Application
  Records and Reports Requirements