DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 11265/S-031

ANI Pharmaceuticals, Inc.
7131 Ambassador Road, Suite 150
Woodlawn, MD 21244

Attention: June Moore
Pharmaceutical Regulatory Specialist

Dear Ms. Moore:

Please refer to your supplemental new drug application dated October 8, 2008, received October 10, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for promethazine hydrochloride and dextromethorphan oral solution.

We acknowledge receipt of your submission dated August 7, 2009.

This "Changes Being Effected" labeling supplement proposes to change the name of the product formulation from "Syrup" to "Oral Solution" and provides for changes to the manufacturer's name and administrative information within the package insert and on the container label. Additionally, this supplement provides for the removal of the Temper evidence statement "*Do not use this product if inner foil seal over the mouth of the bottle is disturbed or missing*" from the container label.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the minor editorial revisions listed below:

1. Delete the reference to HCL in the PRECAUTIONS: Drug Interactions: *CNS Depressants* section in the sentence " Promethazine may increase…therefore, such agents should be avoided or administered in reduced dosage to patients receiving promethazine ~~HCL~~."

2. Un-capitalize the "P" in Promethazine in the second paragraph of the PRECAUTONS: Pregnancy: Teratogenic Effects-Pregnancy Category C section.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to, except for including the revisions listed, the enclosed text for the package insert submitted August 7, 2009. These revisions are terms of the NDA approval. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "**SPL for approved NDA 11265/S-031."**

We acknowledge your October 8, 2008, submission containing final printed container labels.

Marketing the products with FPL that is not identical to the approved labeling text may render the products misbranded and an unapproved new drug.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Philantha Bowen, Regulatory Project Manager, at (301) 796-2466.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, MD, Ph.D.
Director
Division of Pulmonary and Allergy Products
Office of Drug Evaluation
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-11265	SUPPL-31	ANI PHARMACEUTICALS INC	PHENERGAN W/ DEXTROMETHORPHAN

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

BADRUL A CHOWDHURY
09/16/2009