DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 08-381/S-28
NDA 11-265/S-29

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

Attention: Nitin Borkar, Ph.D
Senior Vice-President

Dear Dr. Borkar:

Please refer to your supplemental new drug applications dated September 28, 2007, and October 2, 2007, received October 2, 2007, and October 3, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for promethazine hydrochloride plain syrup and promethazine hydrochloride and dextromethorphan hydrobromide syrup

We acknowledge receipt of your submission(s) dated March 26, 2008, and March 31, 2008.

These "Changes Being Effected-30" supplemental new drug applications provide changes to the manufacturing site, packaging and test method of the finished product. In addition, this supplement provides for the addition of a Boxed Warning to the package insert, and changes to the storage conditions, product name, manufacturer's name, and administrative information in the package insert and on the container label.

We have completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50 (1)] in structured product labeling (SPL) format submitted on March 31, 2008.

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).

Submit final printed container labels that are identical to the submitted immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format-Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**Final Printed Container Labels for approved NDAs 08-381/S-028 and 11-265/S-029**."

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 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

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

/s/

Badrul Chowdhury

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