



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 08-306/S-030

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 application dated November 16, 2007, received November 20, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Promethazine and Codeine Syrup and Promethazine, Phenylephrine, and Codeine Syrup.

We acknowledge receipt of your submissions dated April 4, 2008, and May 23, 2008.

Your submission of May 23, 2008, constituted a complete response to our May 19, 2008, action letter.

This "Changes Being Effected" supplemental new drug application provides for changes throughout the label, including the addition of a boxed warning and changes to the DESCRIPTION, CLINICAL PHARMACOLOGY, CONTRAINDICATIONS, WARNINGS, ADVERSE EVENTS, OVERDOSAGE, PRECAUTIONS, DOSAGE AND ADMINISTRATION, and HOW SUPPLIED Sections of the package insert. In addition, this supplement provides for changes to the manufacturer's name and removing the proprietary name from the labeling.

We have completed our review of these applications, as amended. This application is approved, effective on the date of this letter, for use as recommended in the enclosed agreed upon labeling text.

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 the submitted labeling (dated May 23, 2008). 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 08-306/S-030.**"

We acknowledge your May 23, 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

**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
11/26/2008 09:37:19 AM