



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 16-199/S-035

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

Attention: Nitin Borkar, Ph.D.  
Senior Vice President  
Product Development & Scientific Affairs

Dear Dr. Borkar:

Please refer to your supplemental new drug application dated September 21, 2007, received September 25, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for CORTENEMA® (hydrocortisone rectal suspension), 100 mg/60mL retention enema.

This "Changes Being Effected" supplemental new drug application provides for revisions to the **DESCRIPTION, CLINICAL PHARMACOLOGY, WARNINGS, PRECAUTIONS, and HOW SUPPLIED** sections of the package insert.

We have completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert and patient instructions submitted on September 21, 2007).

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

Please submit one market package of the drug product when it is available.

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 Lauren Tornetta, Regulatory Project Manager, at (301) 796-2246.

Sincerely,

*{See appended electronic signature page}*

Bob Rappaport, M.D.  
Director  
Division of Anesthesia, Analgesia  
and Rheumatology Products  
Office of Drug Evaluation II  
Center for Drug Education and Research

Enclosure (labeling)

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

/s/

-----  
Rigoberto Roca  
2/21/2008 09:34:34 AM  
for Bob Rappaport, M.D.