DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 17854/S-056

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT
REMS ASSESSMENT ACKNOWLEDGMENT
PRIOR APPROVAL SUPPLEMENT REQUEST

ANI Pharmaceuticals Inc.
Attention: Robert Jannick
Vice-President, Quality & Product Development
210 West Main Street
Baudette, MN 56623

Dear Mr. Jannick:

Please refer to your Supplemental New Drug Application (sNDA) dated April 28, 2011, and received April 29, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Reglan (metoclopramide) Tablets, USP.

We also refer to your submission dated March 3, 2011, containing your risk evaluation and mitigation strategy (REMS) assessment for Reglan (metoclopramide).

In accordance with Section 505-1(h)(2) of the FDCA, we notified you that we were initiating discussions of your REMS assessment through a letter dated May 3, 2011. After consultation between the Office of Surveillance and Epidemiology and the Office of New Drugs, we found the REMS assessment to be complete.

In addition, we proposed revisions to the Medication Guide in an email dated May 12, 2011, and you agreed to these revisions in your correspondence dated May 19, 2011.

This supplemental new drug application proposes to eliminate the requirement for the approved Reglan (metoclopramide) REMS.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter.

Please submit your agreed upon changes to the Medication Guide as stated in your May 19, 2011, correspondence as a Prior Approval Labeling Supplement within 14 days of receipt of this letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Reglan (metoclopramide) was originally approved on September 4, 2009. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for Reglan (metoclopramide).

We have determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern and meets the standard in 21 CFR 208.1. Therefore, we agree that it is no longer necessary to include the Medication Guide as an element of the approved REMS to ensure that the benefits of Reglan (metoclopramide) outweigh its risks, and a REMS for Reglan (metoclopramide) is no longer required.

We remind you that the Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR 208.

REPORTING REQUIREMENTS

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 Maureen Dewey, Regulatory Project Manager, at (301) 796-0845.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director for Safety
Division of Gastroenterology and Inborn Errors Products
Office of Drug Evaluation III
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/

JOYCE A KORVICK
08/02/2011