DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-854/S-051
NDA 21-793/S-004

Alaven Pharmaceuticals, LLC
Attention: Mary Alonso
Director, Quality Assurance and Regulatory Affairs
200 North Cobb Parkway, Suite 428
Marietta, GA 30062

Dear Ms. Alonso:

Please refer to your supplemental NDA 17-854/S-051 for Reglan (metoclopramide) Tablets and supplemental NDA 21-793/S-004 for Reglan ODT (metoclopramide) Orally Disintegrating Tablets submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA).

We acknowledge receipt of your submissions dated March 3, March 25, May 12, May 15, June 23, June 25, June 26, 2009.

Reference is also made to our letter dated February 26, 2009 notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for Reglan (metoclopramide) Tablets and Reglan ODT (metoclopramide) Orally Disintegrating Tablets. This information pertains to the risk of tardive dyskinesia.

These supplemental new drug applications provide for revisions to the labeling for Reglan (metoclopramide) Tablets and Reglan ODT (metoclopramide) Orally Disintegrating Tablets consistent with our February 26, 2009, letter and correspondences between FDA and Alaven dated March 30, May 6, May 18, June 18, June 24, June 26, 2009.

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

Your approved Medication Guide will become part of the Risk Evaluation and Mitigation Strategy (REMS) **(b) (4)**

CONTENT OF LABELING

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 attached labeling and Medication Guide.

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 17-854(b) (4) and NDA 21-793(b) (4) ."** In addition, within 21 days of the date of this letter, amend any pending supplement for these NDAs.

We request that the revised labeling approved today be available on your website within 10 days of receipt of this letter.

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

Please note that:

- this Medication Guide must be reprinted immediately following the last section of labeling or, alternatively, accompany the prescription drug labeling [21 CFR 201.57(c)(18) or 21 CFR 201.80(f)(2)];

- you are responsible for ensuring that this Medication Guide is available for distribution to every patient who is dispensed a prescription for this product [21 CFR 208.24];

- the final printed Medication Guide distributed to patients must conform to all conditions described in 21 CFR 208.20, including a minimum of 10 point text; and

- you are responsible for ensuring that the label of each container or package includes a prominent and conspicuous instruction to authorized dispensers to provide a Medication Guide to each patient to whom the drug is dispensed, and states how the Medication Guide is provided [21 CFR 208.24(d)]

LETTER TO HEALTH CARE PROFESSIONALS

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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure: Package Insert and Medication Guide

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

/s/

Joyce Korvick

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