



ANDA 74-703/S-007

APPROVAL LETTER

Morton Grove Pharmaceuticals, Inc.
Attention: Ralph J. Hodosh, Ph.D.
Director, Regulatory Affairs
6541 West Main Street
Morton Grove, IL 60053

Dear Dr. Hodosh:

Please refer to your supplemental ANDA 74-703/S-007 for Metoclopramide Oral Solution USP, 5 mg/5 mL, submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FDCA), dated March 26, 2009.

We acknowledge receipt of your submissions dated March 26, April 16, May 12, June 10, June 26, and July 16, 2009.

This supplemental new drug application provides for a proposed Risk Evaluation and Mitigation Strategy (REMS) for Metoclopramide Oral Solution as requested in our letter dated February 26, 2009.

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

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

Section 505-1 of the Federal Food, Drug, and Cosmetic Act (FDCA) authorizes FDA to require the submission of a Risk Evaluation and Mitigation Strategy (REMS) if FDA becomes aware of new safety information and makes a determination that such a strategy is necessary to ensure that the benefits of the drug outweigh the risks (section 505-1(a)).

Metoclopramide Oral Solution USP, 5 mg/5 mL, was approved on October 31, 1997. Current product labeling warns of the risk of tardive dyskinesia, a serious movement disorder, with chronic metoclopramide treatment. Tardive dyskinesia is often irreversible. Several risk factors, including female gender, advanced age, treatment duration and total cumulative dose have been described. Recently published analyses suggest that metoclopramide has surpassed haloperidol as the most common cause of drug-induced movement disorders. A published FDA analysis of metoclopramide utilization patterns showed that prescription claims for cumulative periods longer than 90 days were recorded for a substantial portion of patients in that study. In addition, we have

become aware of continued spontaneous reports to the FDA of tardive dyskinesia associated with metoclopramide use. Exposure greater than 12 weeks was evident in a majority of these reports. This information was not available when Metoclopramide Oral Solutions were granted marketing authorization. We consider this information to be “new safety information” as defined in FDAAA.

Your proposed REMS, submitted on March 26, 2009, and amended on July 16, 2009, is appended to this letter, and is approved. The REMS consists of a Medication Guide.

We remind you that you must propose a modification to the approved REMS when you submit a supplemental application.

Prominently identify the submission containing the proposed REMS modifications with the following wording in bold capital letters at the top of the first page of the submission:

**NEW SUPPLEMENT FOR ANDA 74-703
PROPOSED REMS MODIFICATION**

If you do not submit electronically, please send 5 copies of REMS-related submissions.

PROMOTIONAL MATERIALS

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the following address or by facsimile at 301-847-8444:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

In addition, as required under 21 CFR 314.81(b)(3)(i), you must submit your updated final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA-2253, directly to the above address. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

LETTER TO HEALTHCARE 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 ANDA and a copy to the following address:

MedWatch
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

REPORTING REQUIREMENTS

We remind you that you must comply with the reporting requirements for an approved ANDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Sarah Park, Labeling Reviewer, at (240) 276-8995.

Sincerely,

{See appended electronic signature page}

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

Enclosure: REMS documents

Application
Type/Number

Submission
Type/Number

Submitter Name

Product Name

ANDA-74703

SUPPL-7

MORTON GROVE
PHARMACEUTICA
LS INC

METOCLOPRAMIDE
HYDROCHLORIDE

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

/s/

GARY J BUEHLER

09/15/2009