DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 087294/S-028

SUPPLEMENT APPROVAL

Morton Grove Pharmaceuticals Inc.
U.S. Agent for Wockhardt Bio AG
6451 Main Street
Morton Grove, IL 60053

Attention: Poonam Kumar
Associate VP, Regulatory Affairs and Analytical Development

Dear Ms. Kumar:

Please refer to your Supplemental Abbreviated New Drug Application (sANDA) dated August 25, 2016, submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Hydroxyzine Hydrochloride Oral Solution USP, 10 mg/5 mL (2 mg/mL).

We acknowledge receipt of your amendment dated October 10, 2016.

We also refer to our letter dated August 11, 2016, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for Hydroxyzine Hydrochloride Oral Solution, USP. This information pertains to an association between hydroxyzine and acute generalized exanthematous pustulosis (AGEP).

Further reference is made to the email from Carol Lee dated October 5, 2016, notifying you that the labeling language proposed in the August 11, 2016, letter had been revised.

This supplemental abbreviated new drug application provides for revisions to the labeling for Hydroxyzine Hydrochloride Oral Solution, USP, consistent with our August 11, 2016, Safety Labeling Change Notification Letter and October 5, 2016, email.

We have completed the review of this supplemental application, as amended. It is approved effective on the date of this letter. However, please make the following revisions to the labeling and submit them in your next Annual Report, provided the changes are described in full.

ADVERSE REACTIONS

1. ADVERSE REACTIONS – Skin and appendages
   We acknowledge that "pruritis, rash, urticaria" were not included in the previously approved labeling. Upon further evaluation, it was determined that these adverse reactions should be included in the labeling for oral solution also. Please add "Pruritis, rash, urticaria" to the end of this subsection.

2. Please note that we did not review the container labels that you submitted in this supplement. The purpose of this supplement is for the safety labeling changes only. You may submit separate supplement for all other changes.
3. Include SPL whenever you submit supplement for labeling changes.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

PROMOTIONAL MATERIALS

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Office of Prescription Drug Promotion with a completed Form FDA 2253 at the time of their initial use.

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1 of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the Federal Register notice announcing facility fee amounts. All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded.

This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

REPORTING REQUIREMENTS

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

The material submitted is being retained in our files. If you have any questions, contact Kyle Snyder, Labeling Project Manager, at (240) 402-8792 or kyle.snyder@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Edward M. Sherwood
Director
Office of Regulatory Operations
Office of Generic Drugs
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/

CAROL A HOLQUIST
11/08/2016