DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

ANDAs 040432/S-006 (7.5 mg/325 mg), 040556/S-012 (10 mg/300 mg),
040658/S-006 (5 mg/300 mg), 40846/S-005 (2.5 mg/325 mg) and
089699/S-044 (7.5 mg/500 mg)

SUPPLEMENT APPROVALS

Mikart, Inc.
Attention: Jason Waldroup
1750 Chattahoochee Avenue
Atlanta, GA 30318

Dear Sir:

Please refer to your supplemental Abbreviated New Drug Applications (sANDAs) dated August 30, 2013, submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Hydrocodone Bitartrate and Acetaminophen Tablets, 2.5 mg/325 mg, 5 mg/300 mg, 7.5 mg/325 mg, 7.5 mg/500 mg and 10 mg/300 mg.

We also refer to our letter and email correspondence dated August 1, 2013, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for acetaminophen-containing products. This information describes the risk of serious skin reactions with the use of acetaminophen-containing products, based on new safety information about this risk identified since the product was approved.

These supplemental new drug applications provide for revisions to the labeling for Hydrocodone Bitartrate and Acetaminophen Tablets consistent with our letter and email correspondence dated August 1, 2013.

We have completed our review of these supplemental applications. They are approved, effective on the date of this letter. However, please make the following post approval revisions to the insert labeling:

WARNINGS, Serious Skin Reactions subsection:

Revise "…can cause serious…" to read "…may cause serious…" in the first sentence.

These changes should be reflected in your structured product labeling (SPL) when submitting it within 14 days of approval and should also be reported in your next annual report with the changes described in full.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in SPL format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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 from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this ANDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in 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 address above or by fax to 301-847-8444.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved ANDA (21 CFR 314.80 and 314.81).

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 dose form (FDFs) or active pharmaceutical ingredient (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.

If you have any questions, contact Carrie Lemley, Labeling Project Manager, at (240) 276-8986 or carrie.lemley@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Kathleen Uhl, M.D.
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research

Enclosure(s):
Content of Labeling

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

/s/

ROBERT L WEST

10/18/2013

Deputy Director, Office of Generic Drugs, for
Kathleen Uhl, M.D.