



ANDA 204209

ANDA APPROVAL

Sovereign Pharmaceuticals, LLC
U.S. Agent for Larken Laboratories, Inc.
7590 Sand Street
Fort Worth, TX 76118
Attention: Leonard Lawrence, BS, MBA, RAC
Manager, Regulatory Affairs

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for Acetaminophen, Caffeine and Dihydrocodeine Bitartrate Tablets, 325 mg/30 mg/16 mg.

Reference is also made to your amendments dated October 15, 2012; April 14 and September 10, 2014; May 14, July 30 and September 17, 2015; and April 29, 2016.

Reference is also made the ANDA Suitability Petition (FDA-2011-P-0096) submitted on February 15, 2011, under Section 505(j)(2)(c) of the Act, and approved on September 27, 2012. This petition requested the Agency to make a determination that your application for Acetaminophen, Caffeine and Dihydrocodeine Bitartrate Tablets, 325 mg/30 mg/16 mg was suitable for filing as an ANDA. This determination was necessary because acetaminophen content provided in your Acetaminophen, Caffeine and Dihydrocodeine Bitartrate Tablets, 325 mg/30 mg/16 mg as proposed in your ANDA differs from the acetaminophen content (712.8 mg) provided by the reference listed drug product. The Agency reviewed the ANDA Suitability Petition and determined that the change in strength (acetaminophen content) requested is the type of change that is authorized under the Act. This determination allows the Agency to approve this ANDA that references the discontinued drug product.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. **Accordingly the ANDA is approved**, effective on the date of this letter. The drug product, Acetaminophen, Caffeine and Dihydrocodeine Bitartrate Tablets, 325 mg/30 mg/16 mg can be expected to have the same therapeutic effect as that of the listed drug product upon which the agency relied as the basis of safety and effectiveness. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

We note that the reference listed drug product (RLD) upon which you have based this ANDA, Mikart Inc.'s Acetaminophen, Caffeine and Dihydrocodeine Bitartrate Tablets, 712.8 mg/60 mg/32 mg, is no longer being marketed in the United States and is currently listed

in the discontinued section of the Agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book").

We refer to the Federal Register notice dated January 14, 2011 (Vol. 76, No. 10, Docket No. FDA-2011-N-0021) in which the Agency announced it was taking steps to reduce the maximum dosage unit strength of acetaminophen in prescription drug products to help prevent liver damage due to acetaminophen overdosing. Sponsors of approved prescription drug products containing more than 325 milligrams (mg) of acetaminophen were asked to request that FDA withdraw approval of their products.

Under section 506A of the FD&C Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the FD&C Act.

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.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling materials prior to publication or dissemination. Please note that these submissions are voluntary. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert, Medication Guide, and patient PI (as applicable) to:

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

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at:

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf>).

You must also 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/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>.

Information and Instructions for completing the form can be found at

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>. 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>.

ANNUAL FACILITY FEES

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.

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.

The Electronic Common Technical Document (eCTD) is CDER's standard format for electronic regulatory submissions. Beginning May 5, 2017 ANDA and Master Files must be submitted in eCTD format. Submissions that do not adhere to the requirements stated in the eCTD Guidance will be subject to rejection. For more information please visit: www.fda.gov/ectd.

Sincerely yours,

{See appended electronic signature page}

Carol A. Holquist, RPh
Acting Deputy Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research



Carol
Holquist

Digitally signed by Carol Holquist
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