



ANDA 204785

WraSer Pharmaceuticals, LLC
Attention: Heath Wray
President and CEO
121 Marketridge Drive
Ridgeland, MS 39157

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated August 31, 2012, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Trezix Capsules (Acetaminophen, Caffeine and Dihydrocodeine Bitartrate Capsules), 320.5 mg/30 mg/16 mg.

Reference is also made to the Complete Response letter issued by this office on April 11, 2014, and to your amendments dated May 21, July 7, July 10, and August 6, 2014.

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 Capsules, 320.5 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.

We note that the reference listed drug product (RLD) upon which you have based this ANDA, Acetaminophen, Caffeine and Dihydrocodeine Bitartrate Capsules, 320.5 mg/30 mg/16 mg, is no longer being marketed in the United States. Thus, WraSer Pharmaceuticals, LLC's Acetaminophen, Caffeine and Dihydrocodeine Bitartrate Capsules, 356.4 mg/30 mg/16 mg, have been moved to 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.

Reference is also made the ANDA Suitability Petition (2011-P-0728) submitted on October 6, 2011, under Section 505(j)(2)(c) of the Act, and approved on July 7, 2012. This petition requested the agency to make a determination that your application for Acetaminophen, Caffeine and Dihydrocodeine Bitartrate Capsules, 320.5 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 Capsules, 320.5 mg/30 mg/16 mg as proposed in your ANDA differs from the acetaminophen content (356.4 mg) provided by the reference listed drug product. The agency reviewed the ANDA Suitability Petition and determined that the change in strength (acetaminophen content) you have 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.

Under section 506A of the 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 Act.

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 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 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.

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.

Sincerely yours,

Robert L.
West -S

 Digitally signed by Robert L. West -S
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ou=FDA, ou=People, cn=Robert L. West -
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For CAPT Jason J.Y. Woo, M.D., M.P.H.
Acting Director, Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research