DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 040445

Sandoz Inc.
Attention: Marcy Macdonald
Director, Regulatory Affairs
4700 Sandoz Drive
Wilson, NC 27893

Dear Madam:

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 (the Act), for Metaxalone Tablets, 800 mg, an amendment for which was received on November 4, 2004.[1]

Reference is also made to your amendments dated November 8, 2001; June 19, June 21, July 16, October 24, November 15, and December 4, 2002; January 7, 2003; May 10, November 1, and December 15, 2004; September 6, 2006; February 2, 2007; January 26, August 29, 2008; and November 23, December 8, December 23, 2009; January 14, January 27 (2 submissions), and March 9, 2010.

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 Division of Bioequivalence has determined your Metaxalone Tablets, 800 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Skelaxin Tablets of King Pharmaceuticals, Inc. (King). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

[1] ANDA 040445 was submitted on August 31, 2001 for a 400 mg. strength which was later withdrawn.

The reference listed drug (RLD) upon which you have based your ANDA, King's Skelaxin Tablets, 800 mg, is subject to periods of patent protection. The following patents and their expiration dates are listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for this drug product:

U.S. Patent Number	Expiration Date
6,407,128 (the '128 patent)	December 3, 2021
6,683,102 (the '102 patent)	December 3, 2021
7,122,566 (the '566 patent)	February 6, 2026

With respect to all three patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Metaxalone Tablets, 800 mg, under this ANDA. You notified the agency that Sandoz complied with the requirements of section 505(j)(2)(B) of the Act, and litigation for infringement of the '128 and '102 patents was brought against Eon Labs (now Sandoz) within the statutory 45-day period in the United States District Court for the Eastern District of New York [King Pharmaceuticals, Inc. v. Eon Labs, Inc., Civil Action No. 04-5540]. You have also notified the agency that the court decided that the '128 and '102 patents are invalid; therefore, under section 505(j)(5)(B)(iii) your ANDA is eligible for approval.[2]

With respect to 180-day generic drug exclusivity for Metaxalone Tablets, 800 mg, the agency has concluded that Sandoz was the first ANDA applicant to submit a substantially complete ANDA for Metaxalone Tablets, 800 mg, with paragraph IV certifications to the '128 and '102 patents. The agency notes that Sandoz failed to obtain tentative approval of this ANDA within 30 months after the date on which the ANDA was filed. We have determined, however, that this was caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application was filed. Namely, Sandoz submitted its amendment for the 800 mg strength on November 4, 2004, and during the entire time the ANDA was under review, the

[2] You also notified the agency that litigation for infringement of the '566 patent was brought against Sandoz in the United States District Court for the District of New Jersey [King Pharmaceuticals Inc., King Pharmaceuticals Research and Development Inc., Pharmaceutical IP Holding Inc. v. Sandoz Inc., Civil Action No. 08-CV-05974-GEB-JJH]. Although this litigation is ongoing, because the '566 patent was listed after submission of your ANDA, litigation with respect to it creates no statutory stay of approval of your ANDA.

agency had pending before it a citizen petition that created a review of the appropriate labeling for generic metaxalone in light of certain patent-protected language in the labeling of the RLD.

Therefore, with this approval, the agency has determined that Sandoz is eligible for 180 days of generic drug exclusivity for Metaxalone Tablets, 800 mg. Generic drug exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, begins to run from the date of commercial marketing identified in that section. Please submit correspondence to this ANDA informing the agency of the date commercial marketing begins.

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
Division of Drug Marketing, Advertising, and Communications
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 Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Within 14 days of the date of this letter, submit updated content of labeling [21 CFR 314.50(1)] 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. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission as ***"Miscellaneous Correspondence – SPL for Approved ANDA 040445".***

Sincerely yours,

{See appended electronic signature page}

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

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
ANDA-40445	ORIG-1	SANDOZ INC	METAXALONE

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
03/31/2010
Deputy Director, for Gary Buehler