DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 090227

Sandoz Inc.
Attention: Jean Domenico
Manager, Regulatory Affairs
2555 W. Midway Blvd.
Broomfield, CO 80038-0446

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated December 13, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Amoxicillin and Clavulanate Potassium Extended-release Tablets, 1000 mg/62.5 mg (base).

Reference is also made to your amendments dated April 17, April 23, June 13, and November 18, 2008; October 9, November 18, and December 3, 2009; and February 5, February 18 March 2, and April 1, 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 Amoxicillin and Clavulanate Potassium Extended-release Tablets, 1000 mg/62.5 mg (base) to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Augmentin XR Tablets, 1000 mg/62.5 mg (base), of GlaxoSmithKline.

Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application. The "interim" dissolution specifications are as follows:

Dissolution testing should be conducted in 900 mL of water at 37°C +/- 0.5°C, using USP apparatus 2 at 75 rpm. The test product should meet the following "interim" specifications:

For Amoxicillin:

Time (hours)	Percent Dissolved
1	(b) (4)
3	(b) (4)
5	NLT (b) (4)

For Clavulanate:

NLT (b) (4) (Q) in 45 minutes

These "interim" dissolution tests and tolerances should be finalized by submitting dissolution data from the first three production size batches. These data should be submitted as a "Special Supplement – Changes Being Effected" if there are no revisions to be made to the "interim" specifications, or if the final specifications are tighter than the "interim" specifications. In all other instances, the information should be submitted in the form of a Prior Approval Supplement.

The reference listed drug (RLD) upon which you have based your ANDA, Augmentin XR Tablets of GlaxoSmithKline, is subject to periods of patent protection. The following U.S. patents with their expiration dates are currently 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
6,746,692 (the '692 patent)	April 4, 2020
6,783,773 (the '773 patent)	April 4, 2020
6,878,386 (the '386 patent)	April 4, 2020
7,217,430 (the '430 patent)	April 4, 2020
7,250,176 (the '176 patent)	April 4, 2020

With respect to each of these patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each of these patents is invalid,

unenforceable, or will not be infringed by your manufacture, use, or sale of Amoxicillin and Clavulanate Potassium Extended-release Tablets under this ANDA. You notified the agency that Sandoz Inc. (Sandoz) complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement was brought against Sandoz within the statutory 45-day period, which action would have resulted in a 30-month stay of approval under section 505(j)(5)(B)(iii).

With respect to 180-day generic drug exclusivity, we note that Sandoz was the first ANDA applicant to submit a substantially complete ANDA with paragraph IV certifications to the patents listed above. Therefore, with this approval, Sandoz is eligible for 180 days of generic drug exclusivity for Amoxicillin and Clavulanate Potassium Extended-release Tablets. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the commercial marketing date identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run.

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.

We 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 505-1(i).

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. For administrative purposes, please designate this submission as "***LABELING/SPL FINAL for Approved ANDA 090227***".

Sincerely yours,

{See appended electronic signature page}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
ANDA-90227	ORIG-1	SANDOZ INC	AMOXICILLIN; CLAVULANATE POTASSIUM

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

04/21/2010

Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.