DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 201525/S-008
NDA 201525/S-009

SUPPLEMENT APPROVAL

Sandoz, Inc.
Attention: Christopher Uhrn
Associate Director, Regulatory Affairs
506 Carnegie Center, Suite 400
Princeton, NJ 08540

Dear Mr. Uhrn:

Please refer to your Supplemental New Drug Applications (sNDA) dated February 25, 2014 and May 15, 2014, received February 25, 2014 and May 15, 2014, respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Docetaxel Injection, 10 mg/mL (20 mg/2 mL, 80 mg/8 mL, 160 mg/16 mL).

We acknowledge receipt of your amendment dated July 10, 2014.

These "Prior Approval" supplemental new drug applications provide for the addition of a new "Eye Disorders" section to WARNINGS AND PRECAUTIONS in the Full Prescribing Information and related language in the Patient Information. In addition, the supplements provide for a new "Metabolism and nutrition disorders" sub-section within the ADVERSE REACTIONS, Postmarketing Experience section of the Full Prescribing Information. Lastly, these supplements implement labeling changes to add a new "Alcohol Content" sub-section to WARNINGS AND PRECAUTIONS. Related language regarding alcohol content has also been added to sub-sections within USE IN SPECIFIC POPULATIONS in the Full Prescribing Information and to the Patient Information.

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

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 structured product labeling (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 NDA, 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).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

REPORTING REQUIREMENTS

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

If you have any questions, call Kim J. Robertson, Regulatory Project Manager, at (301) 796-1441.

Sincerely,

{See appended electronic signature page}

Amna Ibrahim, MD
Acting Director
Division of Oncology Products 1
Office of Hematology and Oncology Products
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/

AMNA IBRAHIM
11/04/2014