DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 125327/20

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING COMMITMENT

BTG International Inc.
Attention: Carol Clark-Evans
Vice President, Regulatory Affairs
5214 Maryland Way #405
Brentwood, TN 37027

Dear Mrs. Evans:

Please refer to your Supplemental Biologics License Application (sBLA), dated September 28, 2012, received September 28, 2012, submitted under section 351(a) of the Public Health Service Act for Voraxaze®.

We acknowledge receipt of your amendment dated March 25, 2013 and March 27, 2013.

This "Prior Approval" supplemental biologics application provides for revisions to the Adverse Reactions section of the package insert to include new information on anti-glucarpidase antibodies following Voraxaze® administration.

We have completed our review of this supplemental application, as amended. It is 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, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (package insert) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. 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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this BLA, including pending "Changes Being Effected" (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] in MS Word format that includes the changes approved in this supplemental application.

REQUIRED PEDIATRIC ASSESSMMENTS

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.

FULFILLMENT OF POSTMARKETING REQUIREMENT(S)/COMMITMENT(S)

We have also received your submission dated March 26, 2013, containing the final report for the following postmarketing requirement listed in the January 17, 2012 approval letter for BLA 125327.

PMC # 3

To analyze patient serum samples from the Voraxaze pivotal studies for the presence of anti-glucarpidase antibodies with neutralizing activity using a validated assay.

We have reviewed your submission and conclude that the above commitment is fulfilled.

We remind you that there are postmarketing requirements and postmarketing commitments listed in the January 17, 2012, approval letter that are still open.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

If you have any questions, call Mona Patel, Pharm.D., Regulatory Project Manager, at (301) 796-4236.

Sincerely,

{See appended electronic signature page}

Jeffery Summers, M.D.
Deputy Director for Safety
Division of Oncology Products 2
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/

JEFFERY L SUMMERS
03/29/2013