



NDA 206353/S-5

SUPPLEMENT APPROVAL

Bristol-Myers Squibb Company
Attention: Maria Wagner, Ph.D.
Global Regulatory, Safety & Biometrics
PO Box 5326
Princeton, NJ 08543-5821

Dear Dr. Wagner:

Please refer to your Supplemental New Drug Application (sNDA) dated and received March 23, 2018, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for EVOTAZ[®] (atazanavir and cobicistat) tablets.

This “Changes Being Effected” sNDA proposes the following changes to the US Prescribing Information (USPI):

- CONTRAINDICATIONS, Section 4: glecaprevir/pibrentasvir and drospirenone/ethinyl estradiol were added to the drugs that are contraindicated with Evotaz
- WARNINGS AND PRECAUTIONS, Section 5: a new subsection 5.5 Chronic Kidney Disease was added to include information consistent with REYATAZ[®] label
- DRUG INTERACTIONS, subsection 7.3: updated with drug interaction information with sofosbuvir/velpatasvir/voxilaprevir, HMG-CoA reductase inhibitors and hormonal contraceptives
- CLINICAL PHARMACOLOGY, subsection 12.3: updated with relevant drug interaction data for atorvastatin, drospirenone/ethinyl estradiol and rosuvastatin
- PATIENT INFORMATION: added drospirenone/ethinyl estradiol (BEYAZ[®], SAFYRAL[®], YASMIN[®], YAZ[®]), elbasvir/grazoprevir (ZEPATIER[®]), and glecaprevir/pibrentasvir to “Who should not take EVOTAZ”; added chronic kidney disease to “What are the possible side effects of EVOTAZ”

APPROVAL & LABELING

We have completed our review of this supplemental application. 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 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, text for the patient 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 include 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).

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 CAPT Anitra Johnson, Regulatory Project Manager, at (301) 796-4876.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Director
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE:
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/

POONAM MISHRA
04/18/2018
on behalf of Debra Birnkrant, MD