



NDA 208216/S-5

SUPPLEMENT APPROVAL

Actavis LLC, an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.
Attention: Scott D. Tomsy,
Vice President, Regulatory Affairs, NA, Generics
400 Interpace Parkway Building A,
Parsippany, NJ 07054

Dear Mr. Tomsy:

Please refer to your supplemental new drug application dated and received April 30, 2020, and your June 4 and June 22, 2020 amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for azacitidine for injection.

This "Changes Being Effected" supplemental new drug application provides for the following changes to the U.S. prescribing information:

- Deletion of Recent Major Changes
- Updates to Actavis LLC company phone number in the Highlights of Prescribing information
- Country of original added to the signature block
- Updates to the Adverse Reactions subsection 6.2 to include Differentiation syndrome
- Removal of reference to section 8.6 listed in the Renal Toxicity subsection of section 12.3 and section 17, and;
- Editorial changes throughout the label.

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling with minor editorial revisions listed below and reflected in the enclosed labeling.

Updated the date at the end of the Highlights of Prescribing Information to " Revised: 7/2020".

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 FDA.gov.¹ Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information), with the addition of any labeling changes in pending “Changes Being Effectuated” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling. If the content of labeling in SPL format initially submitted with this CBE-0 labeling supplement is identical to the attached approved labeling, an additional submission of content of labeling in SPL format is not required.

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.²

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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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).

¹ <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

² We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

If you have any questions you may contact Felicia Diggs, Safety Regulatory Project Manager, at (240) 402-4932 or via email at Felicia.diggs@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Shanthi Marur, M.B.B.S., M.D.
Associate Director for Safety (Acting)
Office of Oncologic Diseases
Center for Drug Evaluation and Research

ENCLOSURE:

- Content of Labeling
 - Prescribing Information

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

SHANTHI N MARUR
07/13/2020 02:14:36 PM