DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 203585/S-006

SUPPLEMENT APPROVAL

Teva Pharmaceuticals GmbH
c/o Teva Branded Pharmaceuticals Products R&D, Inc.
Attention: Michelle Rushanan, MS
Director, Regulatory Affairs
41 Moores Road
P.O. Box 41
Frazer, PA 19355

Dear Ms. Rushanan:

Please refer to your Supplemental New Drug Application (sNDA) dated July 31, 2018, received July 31 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for SYNRIBO (omacetaxine mepesuccinate) for injection, 3.5 mg.

This "Changes Being Effected" supplemental new drug application provides for the following changes to the Instruction for Use:

1. The addition of "*(even if you wear glasses)"* to the sentence "Wearing gloves and protective eyewear *(even if you wear glasses)* protects you from splashes or spills."
2. The addition of "*gloves*" to the sentence "Throw away (dispose of) used Synribo syringes, needles, *gloves*, and other used supplies in appropriate biohazard container."
3. The distributed by Teva logo was revised along with the issued month/year.

APPROVAL & LABELING

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 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 Instructions for Use), 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. 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 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 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).

If you have any questions, call Thomas Iype, Regulatory Project Manager, at (240) 402-6861.

Sincerely,

{See appended electronic signature page}

Albert Deisseroth, MD, PhD
Supervisory Associate Division Director
Division of Hematology Products
Office of Hematology & Oncology Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling
Instructions for Use

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/

ALBERT B DEISSEROTH
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