March 1, 2017

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IMPORTANT DRUG INFORMATION UPDATE

Subject: **Availability of TRISENOX® (arsenic trioxide) Injection**

Dear Healthcare Professional:

In order to alleviate a critical shortage of TRISENOX® (arsenic trioxide) Injection, Teva Pharmaceuticals is coordinating with the U. S. Food and Drug Administration (FDA) to assure uninterrupted availability of this life-saving medicine. Consequently, FDA does not object to the release of TRISENOX Lots 7B05125, 7B05126 and 7B05127 that were manufactured at an alternate manufacturing facility not yet approved by FDA.

Although the manufacturing facility has not been approved by the FDA, the TRISENOX Lots 7B05125, 7B05126 and 7B05127 have undergone a full internal review by Teva to provide assurance that the product meets quality and safety standards. Teva's goal is to supply TRISENOX without interruption to the healthcare providers and patients who need this medication. Teva will continue to seek FDA approval of its new manufacturing site to ensure sufficient supply of TRISENOX for prescribers and their patients as this remains a priority for Teva.

TRISENOX is indicated for the induction of remission and consolidation in patients with acute promyelocytic leukemia (APL) who are refractory to, or have relapsed from, retinoid and anthracycline chemotherapy, and whose APL is characterized by the presence of the t(15;17) translocation or PML/RAR-alpha gene expression.

Please ensure your staff and any provider in your institution who may be involved in the administration of TRISENOX receives a copy of this letter.

For Further Information

Please see the accompanying Full Prescribing Information for complete safety information before prescribing TRISENOX.

If you have any additional questions about product availability or ordering of TRISENOX Injection, please contact Teva Customer Service at 800-545-8800 (Select Option #3, then # 2).

Reporting Adverse Events

Health care providers and patients should report quality problems and all adverse events in patients taking TRISENOX Injection to Teva Pharmaceuticals at 1-888-483-8279, Option #2.

Adverse events or quality problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting Program either online, or regular mail, or by fax:

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Regular mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

You also may contact our medical information department at 1-888-483-8279, Option #2 or at USMedInfo@tevapharm.com if you have any questions about the information contained in this letter or the safe and effective use of TRISENOX Injection.

Please see the enclosed full prescribing information, including boxed warning, for TRISENOX.

Sincerely,

Denisa Hurtukova, MD
Vice President, Head of North America Medical Affairs
Teva Pharmaceuticals

Enclosures: Full prescribing information for TRISENOX® (arsenic trioxide) Injection