



June 15, 2016

IMPORTANT DRUG INFORMATION

Subject: Change in Expiration Date for Bleomycin for Injection, USP

Dear Healthcare Professionals,

The purpose of this letter is to alert you that the expiration date for Bleomycin for Injection, USP, (Bleomycin) lots **6112149** and **6112150** has been changed from a 24 month expiration date to a 12 month expiration date. Due to the current critical shortage of Bleomycin in the U.S. Market, Fresenius Kabi USA, LLC (Fresenius Kabi) has placed a secure sticker over the original product label to reflect the new expiration date and bar code for these two lots.

Fresenius Kabi is releasing lots 6112149 and 6112150 bearing the stickers with the knowledge of the U.S. Food and Drug Administration. Please review the sticker on the carton and vial label for the specific expiration date of the product lot you have received.

Adverse reactions or quality problems experienced with the use of this product should be reported to Fresenius Kabi at the number(s) listed below. 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.

Fresenius Kabi CONTACT NUMBERS: Please use the following contact numbers as appropriate:

| <u>Number</u> | <u>Department</u> | <u>Reason to Call</u> |
|---------------|-------------------------------------|-----------------------------------------------|
| 866-716-2459 | Quality Assurance Department | Information on DHCP Letter |
| 800-551-7176 | Vigilance and Medical Affairs Dept. | Clinical/Technical Information/ADE/Complaints |

Sincerely,

Melanie Power-Burns
Vice President, Quality Assurance
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Fresenius Kabi USA, LLC

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