Human and Animal Sterile Drug Products by I.V. Specialty: FDA Alert - Lack of Sterility Assurance

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AUDIENCE: Pharmacy, Nursing, Veterinary Medicine, Infectious Disease

ISSUE: The U.S. Food and Drug Administration (FDA) is alerting health care professionals and patients not to use drug products intended to be sterile that are produced and distributed by I.V. Specialty Ltd., Austin, Texas, due to lack of sterility assurance. On March 7, 2016, FDA recommended that I.V. Specialty cease sterile production until appropriate corrective actions are implemented, and recall all non-expired drug products intended to be sterile. The company has neither ceased sterile production nor initiated a recall. Therefore, FDA is alerting health care professionals and patients to dispose of and not use drug products intended to be sterile that were produced and distributed by I.V. Specialty.

BACKGROUND: During FDA's recent inspection of I.V. Specialty, investigators observed insanitary conditions, including poor sterile production practices, which raise concerns about I.V. Specialty's ability to assure the sterility of the drug products it produces. Administration of a non-sterile product intended to be sterile may result in serious and potentially life threatening infections or death.

RECOMMENDATION: Health care professionals and consumers should immediately check their medical supplies, quarantine any drug products labeled as sterile from I.V. Specialty, and not administer them to patients. Health care professionals should make alternative arrangements to obtain any medications they administer to patients from reliable sources that adhere to proper quality standards.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form 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

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