

FDA NEWS RELEASE

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FDA announces voluntary nationwide recall by Balanced Solutions Compounding Pharmacy

All sterile non-expired products recalled due to a lack of sterility assurance

Balanced Solutions Compounding Pharmacy (Balanced Solutions), a division of Axiom Healthcare Pharmacy, Inc., of Lake Mary, Fla., is voluntarily recalling all lots of its sterile non-expired drug products due to a lack of sterility assurance and concerns with product quality controls.

Health care facilities and health care providers that have received sterile products from Balanced Solutions should immediately check their medical supplies, quarantine the products, and follow the recall instructions from Balanced Solutions. Patients who were administered any sterile drug products produced and distributed by Balanced Solutions and who have concerns should contact their health care providers.

During an FDA inspection of Balanced Solutions, investigators observed poor practices and conditions, which may have exposed the company's sterile products to microbial contamination. The FDA's preliminary findings of sterile production practices and conditions at the site raise concerns about a lack of sterility assurance. This lack of sterility assurance has been confirmed by further FDA analysis. The FDA sampled chromium chloride injection from Balanced Solutions and identified gram-negative bacteria, a type of contaminant, in the product. Gram-negative bacteria can cause disease and many types of infection, but the *Sphingobacterium thalpophilum* bacteria found in the solution does not usually cause infection in humans.

Adverse reactions experienced by patients using any products made by Balanced Solutions may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Online: www.fda.gov/medwatch/report.htm
- Regular mail: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm and mail to address on the pre-addressed form
- Fax: 1-800-FDA-0178

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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