FDA News Release

FDA alerts health care professionals and patients not to use products from the Prescription Center pharmacy in Fayetteville, N.C.

For Immediate Release

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Release

The U.S. Food and Drug Administration is joining the North Carolina Board of Pharmacy (NC BOP) to urge health care professionals, including veterinarians, and patients not to use products made and distributed by the Prescription Center pharmacy, located at 915 Hay St., Fayetteville, North Carolina.

In an inspection conducted in March by the NC BOP, state inspectors observed significant deficiencies that raise concerns about the company's ability to assure the sterility, stability and potency of the sterile and non-sterile human and veterinary drug products that it produced. The Prescription Center has been closed by order of the NC BOP, and the NC BOP has ordered a recall of all lots of sterile and non-sterile products compounded or repackaged and distributed by the Prescription Center between Sept. 10, 2014, and March 10, 2015.

Drug products made by the Prescription Center have been distributed nationwide and to Canada. Although the FDA is not aware of any adverse events associated with these products, due to concerns about a lack of sterility assurance and other conditions at the facility, and out of an abundance of caution, the FDA and the NC BOP are advising against their use. Health care professionals should check their medical supplies, quarantine any drug products from the Prescription Center and should not administer them to either human or animal patients.

Adverse reactions or quality problems experienced with the use of these products may be reported to the FDA's MedWatch Adverse Event Reporting program:

For reports of adverse events in humans:

- Complete and submit the report online at www.fda.gov/medwatch/report.htm; or download and complete the form, then submit it via fax at 1-800-FDA-0178.

For reports of adverse events in animals:

- Submit FORM FDA 1932a (download PDF), which is a pre-addressed, prepaid postage form that can be completed or dropped in the mail; or
- call the Center for Veterinary Medicine: 1-888-FDA-VETS. Leave your name, address, phone number, and the brand name of the drug involved. Ask to have a Form FDA 1932a sent to you.

Health care professionals and consumers may also report adverse events to the NC BOP:

- Online at complaints@ncbop.org
- Via fax at 919-246-1056

The FDA will continue to work closely with the NC BOP to protect the public health.

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.