August 23, 2013

RE: IMPORTANT INFORMATION REGARDING FDA CONCERNS WITH TESTING BY FRONT RANGE LABORATORIES

Dear Pharmacy Manager,

Your firm has been identified as a past or current customer of Front Range Laboratories, Inc. (Front Range), located in Loveland, Colorado. In an ongoing inspection, U.S. Food and Drug Administration (FDA) investigators have observed that certain methods used by Front Range to assess sterility, endotoxin, and other quality attributes, such as strength, and, in some instances, the firm's improper use of analytical methods, may have resulted in pharmacies receiving inaccurate laboratory test results. FDA investigators have observed that the firm does not comply with either USP standards or FDA's Current Good Manufacturing Practice (CGMP) regulations at 21 C.F.R. Parts 210 and 211. FDA recommends that pharmacies not use this firm for sterility and other quality attributes testing at this time. Please see the following link for a statement by FDA's Center for Drug Evaluation and Research: *http://www.fda.gov/Drugs/DrugSafety/ucm365920.htm*. FDA's investigation is ongoing.

In addition, in certain instances, FDA investigators observed that Front Range may not have adequately investigated laboratory test failures and may have inaccurately reported test results to certain customers (*e.g.*, failing test results were reported to customers as passing results). Consequently, the affected products may not have passed laboratory tests, or may not have passed if those tests had been conducted properly. Front Range has informed FDA that it will contact the affected customers individually regarding failing test results that were reported as passing results. FDA also intends to follow up with these firms regarding the disposition of lots of potentially affected drug products.

You should review your records to determine whether further action is needed to address any risks posed by drug products you are holding or have distributed that are still within expiry. The link provided above also includes information about how to report adverse events that may be related to the use of these products to the FDA's MedWatch program.

Sincerely,

Ilisa Bernstein, Pharm.D., J.D.
Deputy Director, Office of Compliance
Center for Drug Evaluation and Research