Louisiana Board of Pharmacy

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BULLETIN No. 14-02 (corrected)

To: All pharmacies, pharmacists, pharmacy interns, and pharmacy technicians

From: Malcolm J Broussard, Executive Director

Date: January 16, 2014

Re: U.S. Food & Drug Administration (FDA) Actions re Certain Drug Products

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The U.S. Food and Drug Administration (FDA) published notice of its intent to take enforcement action against certain *un*approved prescription drug products on the market. In particular, FDA has announced its intent to take enforcement action against the following *un*approved prescription drug products:

- Single-ingredient codeine sulfate oral tablets and solutions;
- Single-ingredient codeine phosphate injection products;
- Fixed-dose combination products containing codeine phosphate; and
- Fixed-dose combination products containing dihydrocodeine bitartrate.

Please take note the enforcement action is applicable to *un*approved prescription drug products in these categories. We are aware there are some approved prescription drug products in these categories, and this notice does not apply to those approved prescription drug products in these categories.

There is no requirement for the approval status of a prescription drug product to appear on the labeling of that product. Although there may be other resources, one method to check the FDA approval status of a particular drug product is by reviewing the FDA's *Orange Book*. Here is a link to that electronic reference: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm.

Within the January 10, 2014 *Federal Register* notice, the FDA declared the *un*approved prescription drug products in these four categories to be misbranded effective on that date. While we are aware of guidance information posted on the FDA's website indicating any of these products currently in pharmacies may remain until their expiration date, the Louisiana Board of Pharmacy's rule at §2501.B.2 (page 199 in the *Louisiana Pharmacy Law Book*) prohibits the dispensing or possession of misbranded drug products.

Therefore, Louisiana-licensed pharmacists may no longer dispense any prescriptions (new or refill) with any of these misbranded *un*approved prescription drug products. In the event pharmacists have patients with new prescriptions or have refills remaining on previous prescriptions for these products, we encourage you to contact the prescriber to make alternative arrangements. Further, we suggest pharmacies with any remaining stock of these products arrange for the return or disposal of that stock as soon as possible.

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Three years ago, to address concerns for the risk of liver damage from excessive intake of acetaminophen, the FDA requested manufacturers of prescription combination drug products containing acetaminophen to limit the amount of acetaminophen to no more than 325 mg. per tablet or capsule. Further, the FDA suggested compliance by January 14, 2014.

FDA issued a recommendation on January 14, 2014 to health care professionals to discontinue the prescribing and dispensing of prescription combination drug products containing more than 325 mg. acetaminophen per dosage unit. Further, the FDA gave notice of their intent in the near future to withdraw its approval of prescription combination drug products containing more than 325 mg. acetaminophen per dosage unit.

We encourage pharmacists with patients taking prescription combination drug products containing more than 325 mg. acetaminophen per dosage unit to manage their patients' drug therapy appropriately. Contact the prescriber to make appropriate adjustments and obtain new prescriptions as soon as possible, before product availability is compromised.