

FDA's Removal of Unapproved Prescription Drug Products Containing Codeine and Dihydrocodeine from the Market

On January 10, 2014, the FDA announced in the Federal Register that certain products containing codeine and dihydrocodeine are now considered to be misbranded. The FDA has given manufacturers and distributors until February 24, 2014 to stop manufacturing these products and until April 10, 2014 to stop distributing them. The FDA is further strongly encouraging pharmacists who are presented with prescriptions for unapproved codeine and dihydrocodeine products to contact the prescriber and suggest an FDA-approved prescription product.

Since the FDA now considers these products to be misbranded, it is illegal under Minnesota law to distribute or dispense them. However, since the FDA is exercising enforcement discretion in order to allow a period of time during which patients can be switched to other drugs, it seems reasonable for the Board to similarly exercise enforcement discretion. The Board will consider any complaints received about the use of these misbranded products on a case-by-case basis and may decline to take action against a pharmacy or pharmacist, depending on the facts. However, pharmacies would be well advised to stop purchasing the drugs that FDA is now saying are misbranded. Pharmacists would be well advised to contact prescribers to get the patient switched to an alternative product that is FDA approved. Pharmacies should *not* be stocking up on these products with the intent to build up a supply that can be used after manufacturers can no longer legally distribute the products. Per the FDA, there are alternative products that contain codeine and dihydrocodeine that are approved by the FDA for manufacturing and distribution. (There is information on the FDA Web site that explains how to identify approved products).

Links to FDA documents:

Federal Register Notice: <https://www.federalregister.gov/articles/2014/01/10/2014-00257/unapproved-and-misbranded-oral-and-injectable-drugs-labeled-for-prescription-use-containing-codeine>

FDA FAQ:

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/SelectedEnforcementActionsonUnapprovedDrugs/ucm377688.htm>