

From: CDER DRUG INFO <DRUGINFO@fda.hhs.gov<mailto:DRUGINFO@fda.hhs.gov>>

Subject: RE: expired drugs

Date: March 30, 2012 2:25:35 PM CDT

Dear [DELETED]:

Thank you for contacting the Division of Drug Information, in the FDA's Center for Drug Evaluation and Research. We apologize for the delay in responding to your inquiry.

Expired drug products are considered to be adulterated within the meaning of Section 501(a)(2)(B) of the Food, Drug and Cosmetic Act, which states that drugs must be manufactured, processed, packed, and held in conformance with current good manufacturing practice. The holding of drug products past their expiration dates supports the 501(a)(2)(B) charge. Please note that it would not be appropriate to cite a retailer for deviations from the current Good Manufacturing Practice (CGMP) regulations in 21 CFR Parts 210 and 211, because the CGMP regulations apply to drug product manufacturers. Additionally, openly disclosing that the drugs are expired is not any basis for an exemption from the Act. From a public health standpoint, there is no assurance that drug products held past their expiration dates are safe and effective, even if they are OTC drugs.

You may view the Federal Food, Drug and Cosmetic Act at

<http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/default.htm>

Regarding health care professionals, state regulations most likely prohibit the use of expired drug products. Each state has drug regulations and the health care professionals are regulated by the state that licenses the individual. We recommend that you check with the appropriate licensing board and the board of pharmacy in your state regarding the use of expired drug products.

In addition, we appreciate your comments regarding drug shortages. The FDA has an established Drug Shortages Program to respond to drug shortages that have a significant impact on public health. You may learn more about how the FDA handles the drug shortages on the FDA website at

<http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050796.htm>

<<https://mail.miemss.org/exchweb/bin/redir.asp?URL=http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050796.htm>> .

FDA's actions for a drug shortage depends on the specific drug product and the impact on public health. As a policy matter, the FDA will help prevent or alleviate shortages primarily of medically necessary drug products, since these can have significant public health consequences. However, the actions taken to achieve this will be determined case-by-case depending on the