DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

#2889

April 6, 2011

David M. Green, Counsel
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Dear Mr. Green

This is a response to your letter dated September 2, 2010, sent via e-mail through Kai Hunter, Legal Assistant and received by the Food and Drug Administration (FDA), Center for Drug Evaluation and Research, Office of Compliance. In the letter you requested comments relating to proposed regulations pursuant to Pennsylvania's Cancer Drug Repository Program Act, regulation number 16A-5423.

FDA has significant concerns with medication re-use and re-dispensing programs, particularly because of the patient safety risks from drugs that leave control of a pharmacy or pharmacist, or are outside the control of a secure drug supply chain. FDA's Compliance Policy Guide (CPG) 460.300 speaks directly to this issue and can be found at the following link: http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074399.htm.

In part, CPG 460.300 states that a pharmacist should not return drug products to stock once they have been out of the pharmacist's possession because there is no assurance of the strength, quality, purity, or identity of the articles. Many state boards of pharmacy have issued regulations specifically forbidding the practice of restocking products that have been outside the chain of custody. We endorse the actions of these state boards as being in the best interest of public health since some of our investigations in the past have shown that drugs returned by patrons and subsequently resold by the pharmacist were responsible for injuries.

It should be noted that CPG 460.300 is neither statutory nor a FDA regulatory requirement, but does reflect the Agency's current views on these matters. Moreover, FDA does not regulate the practice of medicine and generally defers to states on pharmacy practices such as those proposed in regulation 16A-5423. Having stated FDA's general position on medication re-use and re-dispensing programs, we also have the following input on Pennsylvania's Cancer Drug Repository Program Act, regulation number 16A-5423.

First, we note that the Pennsylvania Board of Pharmacy Code §27.102 "*prohibits the return to stock of medication once it has left the premises of the pharmacy.*" We interpret proposed regulation number 16A-5423 to provide an exception to §27.102. In addition to our general concerns about Pennsylvania's proposed regulation 16A-5423 noted in CPG 460.300, we have

specific comments and concerns relating to §27.502, §27.504, and §27.505 of the proposed regulation.

Under §27.502 , original sealed and tamper-evident unit dose packaging is defined as "*Single unit dose packaging of oral medications from a manufacturer or a repackager licensed with the Federal Food and Drug Administration, or from a licensed pharmacy, and includes injectables, topicals, and aerosols. . ..*" We feel that this statement is confusing because it can be interpreted to mean that oral medications include injectable, topicals, and aerosols. Also, stating that a repackager is licensed with FDA is not accurate. According to the Federal Food, Drug and Cosmetic Act, repackagers are *registered* with the FDA, not licensed. Lastly, the reference to "a licensed pharmacy" in the definition in confusing because it could be interpreted to mean a pharmacy licensed in Pennsylvania, or a pharmacy licensed in any state.

Considering the comments stated above, we suggest §27.502 be revised to read "*Single unit dose packaging of a drug product from a manufacturer or a repackager registered with the Federal Food and Drug Administration, or from a Pennsylvania licensed pharmacy, and includes oral medications, injectables, topicals, and aerosols. . ..*"

Next, under §27.504 we are concerned about detecting whether a product has been tampered with and guaranteeing product quality. Sections 27.504(a)(1)-(2) state that a drug is eligible for the program if it is "*...in its original unopened, sealed and tamper-evident unit dose packaging*" or "*. . . is packaged in single unit doses, when the outside packaging is opened but the single-unit-dose packaging is unopened.*" Our concerns are that even if packaged in a way mandated by §27.504, the receiving pharmacist may not be able to tell if the product or package was further manipulated or if a new tamper-evident feature was added to conceal the manipulation. If this manipulation is concealed, it will be nearly impossible for the pharmacist to detect through visual inspection if product quality or integrity has been compromised. Moreover, counterfeiters are becoming increasingly sophisticated, and are now able to produce convincing counterfeits of manufacturer packaging thereby necessitating even greater vigilance on the part of pharmacists.

Finally, under §27.505 (e)(4) the informed consent form shall include a statement that indicates "*[t]hat a visual inspection has been conducted by the pharmacist to ensure that the drug has not expired, has not been adulterated or misbranded, and is in its original, unopened packaging.*" We refer to FDA's position outlined in CPG 460.300 that it is impossible to determine all types of adulterations or misbranding based upon visual inspection alone as stated in §27.505 (e)(4). Rather, complex laboratory analyses of the product would be needed to insure the integrity of the products. The FDA would rather see language in this section and throughout proposed regulation 16A-5423 that is consistent with FDA views expressed in CPG 460.300.

Thank you for contacting FDA on these matters. Please feel free to contact me if we can provide additional input or be of further assistance in any way.

Sincerely yours,

Michael M. Levy, Director
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Office of Compliance
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Food and Drug Administration