DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

SEP 15 2014

The Honorable H. Morgan Griffith
House of Representatives
Washington, D.C. 20515-4609

Dear Mr. Griffith:

Thank you for your letter of June 27, 2014, cosigned by 30 of your colleagues, in which you request clarification regarding the Food and Drug Administration's (FDA or Agency) intention to regulate community-based pharmacists in their role of providing physicians, hospitals, and other health care settings with compounded medications for administration and treatment of patients within their practice settings, commonly referred to as "office use." You also express your support for allowing repackaging of finished FDA-approved pharmaceuticals.

We appreciate your interest in these issues and in implementation of the Drug Quality and Security Act (DQSA). Since the passage of the DQSA in November, 2013, FDA has been developing the regulatory framework to implement the Act. We have issued policy documents relating both to amended section 503A and the new section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (see *http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/default.htm)*.

FDA has also met with numerous stakeholders. We convened a 50-state meeting on March 20-21, 2014, to discuss implementation of the Compounding Quality Act with our state partners. During June and July, FDA held listening sessions with over 40 stakeholders.

With respect to drugs for office use, section 503A requires that to qualify for exemptions from certain requirements, such as having to submit a new drug application, a compounder must obtain a prescription for an individually identified patient. In the DQSA, Congress did not change the part of the law that speaks to the need for a prescription. Both before and after the passage of the DQSA, FDA has issued Warning Letters to firms that were not getting prescriptions for individually identified patients. The Agency intends to continue to exercise its authority, as appropriate, to protect the public health.

The Agency has begun to review its policies with respect to compounding and repackaging of drug products, including biological products, taking into consideration the best interest of patients and the recent passage of the DQSA. FDA will communicate the results of its review to all interested stakeholders as soon as it is able to do so. We would be happy to provide a briefing to you or your staff at that time.

Thank you for your interest in this matter. The same response has been sent to your cosigners.

Sincerely,

Thomas A. Kraus
Associate Commissioner
for Legislation