ANGELA LOG

DEPARTMENT OF HEALTH & HUMAN SERVICES

OCT 12 2010

Food and Drug Administration
Rockville MD 20857

OCT 14 2010

Roger L. Williams, M.D.
Chief Executive Officer, USP
12601 Twinbrook Parkway
Rockville, MD 20852

Dear Dr. Williams:

This letter is to emphasize the importance of drug monographs to FDA in ensuring the quality and safety of all drug products and to reiterate FDA's interest in continuing to collaborate with USP to achieve this objective.

USP has an extremely important role in protecting the public health through the issuance of new and up-to-date standards for use by the industry in testing products for quality and safety. It is, therefore, imperative for USP to devote the necessary time and resources in order for this important obligation to be met. I'd like to encourage USP to continue to move forward with its monograph modernization initiative, which was announced in April 2010, and to assure you that FDA fully supports your efforts.

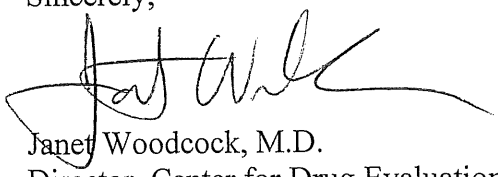
Recent collaborative efforts between FDA and USP (e.g., Heparin and Melamine contamination; heavy metals analytics) were successful; however, we believe this is only a small indication of the problems that actually exist because of outdated monographs. FDA will continue to be proactive in its efforts to ensure that quality products are on the market but we rely on USP to ensure that monographs are updated in a timely manner to help make this happen.

We believe that USP's current monograph modernization program is a good start toward achieving our objective. However, it is important that the initiative be completed with urgency and that USP's efforts focus on drug products and ingredients that have the most potential for problems. In addition to the currently identified "top 200 small molecules monographs and 96 excipient monographs," we encourage USP to update all monographs that include non-specific assay or identification tests, and to re-evaluate antiquated methodologies in general. FDA strongly believes that monographs utilizing outdated analytical procedures are vulnerable to economically motivated adulteration (EMA), and current advancements in science and technology can help to fill the void. We are similarly concerned about outdated OTC monographs, and will be sending you our expert input on OTC monographs that need to be revised.

FDA has established a new task group in CDER to focus on the USP monograph modernization initiative. This group is responsible for developing a strategy to identify priority products for monograph modernization to provide requested FDA assistance to USP in your modernization efforts.

FDA appreciates your current efforts toward monograph modernization and looks forward to continued collaboration on this and other projects at USP. Please feel free to contact me if there are any comments or questions. CDER staff looks forward to discussing the modernization initiative further at the next FDA/USP quarterly meeting in October.

Sincerely,



Janet Woodcock, M.D.
Director, Center for Drug Evaluation and Research
Food and Drug Administration

Cc: Angela Long
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