



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

COPY

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Ms. Angela G. Long  
Executive Secretariat  
The United States Pharmacopeial Convention, Inc.  
12601 Twinbrook Parkway  
Rockville, MD 20852

REF: 11-10-001-S

Dear Ms. Long:

This is in regard to the October 12, 2010 correspondence from Dr. Janet Woodcock to USP on the importance of monograph modernization. Specifically, FDA has established a new task group to focus on the USP monograph modernization initiative.

The Task Group aims to identify USP/NF monographs in need of modernization and is especially focused on monographs with outdated analytical methods that may make the drug or excipient vulnerable to economically-motivated adulteration (EMA) or that have inadequate tests. This is in keeping with resolutions adopted by USP at its April 2010 Convention to work to modernize its monographs as a priority in its work plan for the next five years.

Attached is a list of drug and excipient monographs that, for the reasons cited in the spreadsheet, we have determined to be most in need of modernization. Additional articles may follow. We hope you will find this useful in your revision efforts.

Please feel free to contact Larry Ouderkirk at 301-796-1585 or Paul Seo at 301-796-4874 if there are any questions. Please use the reference number provided above on any ensuing correspondence.

Sincerely,

Larry Ouderkirk  
Co-Chair, Monograph Modernization Task Group  
Office of Compliance  
Center for Drug Evaluation & Research

Paul Seo, Ph.D.  
Co-Chair, Monograph Modernization Task Group  
Office of Pharmaceutical Science  
Center for Drug Evaluation & Research

Attachment

**Attachment: List and Rationale of Drug and Excipient Monographs Most in Need of Modernization**

<b>Monograph(s)</b>	<b>Rationale</b>	
Acetaminophen (drug substance)		
Acetaminophen Oral Suspension; Acetaminophen Oral Solution; Acetaminophen for Effervescent Oral Solution		
Oral Solution Containing at Least Three of the Following— Acetaminophen and Salts of Chlorpheniramine, Dextromethorphan, and Pseudoephedrine		
Acetaminophen, Dextromethorphan Hydrobromide, Doxylamine Succinate, and Pseudoephedrine Hydrochloride Oral Solution		
Acetaminophen Tablets		
Acetaminophen Capsules		
Diphenhydramine Hydrochloride		
Diphenhydramine and Pseudoephedrine Capsules		

Povidone; Crospovidone; Copovidone	Nitrogen assay test is nonspecific and it would be preferred to have a more specific assay due to concerns about EMA involving e.g. melamine. Monographs for 3 Povidone analogs are not consistent with respect to the impurity specifications and should be harmonized within USP and to the EP monographs (e.g. Limit of hydrazine; limit of aldehydes; limit of peroxides (estimate based on absorbance value); heavy metals (estimate using 5 ppm and 10 ppm stds) and EP monographs)
Talc	Labeling should be revised to match the statements that are provided in the Talc FCC monograph, thereby assuring that Talc is not sourced from mines that are known to contain asbestos. Also, USP should consider revising the current tests for asbestos to ensure adequate specificity.