

Food and Drug Administration
Rockville MD 20857

AUG 22 2011

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

REF: 8-11-003-S

Dear Ms. Long:

This is correspondence in follow-up to our November 16, 2010, correspondence (FDA Ref: 11-10-001-S) regarding USP monographs in need of modernization. The FDA Monograph Modernization Task Group (MMTG) has recently identified from your lists several monographs that we believe should be moved up in prioritization as candidates for modernization. These are listed alphabetically, below:

- Albuterol (Sulfate)
- Chlorpheniramine (Maleate)
- Ciprofloxacin (HCl)
- Cephalexin
- Dextromethorphan (HBr)
- Metoprolol (Tartrate)
- Phenylephrine (HCl)
- Promethazine (HCl)
- Pseudoephedrine (HCl + Sulfate)
- Warfarin (Sodium)

The Task Group focused on your established lists of determined monograph titles in need of modernization (outdated analytical methods and/or missing or inadequate tests, etc.). The review ranked APIs on your lists by usage data (IMS); we have alphabetically listed the top 10 APIs from that review. Please also review for possible prioritization of any associated drug product monographs utilizing the listed APIs.

As we continue to refine our approach, we plan to identify additional priority monographs for modernization. We hope you will find this useful in your revision efforts. We also plan to send separately our suggestions for appropriate prioritization of excipient monographs in need of modernization.

Additionally, we note that there are several drug substance and drug product monographs on your "Monographs in Need of Modernization" list (last updated 29-July-2011) that, according to information published in the FDA "Orange Book," are no longer marketed in the United States (e.g., Azatadine Maleate or Benoxinate Hydrochloride). We recommend that after your review of the Orange Book you remove these and any other monographs for non-marketed drug substances and drug products from consideration for modernization at this time.

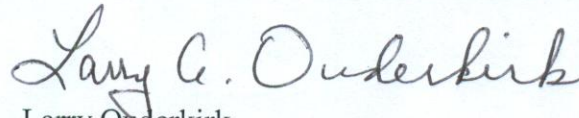
Please feel free to contact Larry Ouderkirk at 301-796-1585 or Paul Seo at 301-796-4874 if there are any questions. Please use the reference number provided above on any ensuing correspondence.

Sincerely,



Paul Seo, Ph.D.

Co-Chair, Monograph Modernization Task Group
Office of Pharmaceutical Science
Center for Drug Evaluation & Research



Larry Ouderkirk

Co-Chair, Monograph Modernization Task Group
Office of Compliance
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