



JUL 2 2012

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

REF: 6-12-002-S

Dear Ms. Long:

This is a follow-up to our November 16<sup>th</sup>, 2010, and August 29<sup>th</sup>, 2011 correspondences (FDA Ref: 11-10-001-S and 8-11-003-S, respectively) regarding USP-NF monographs in need of modernization. The FDA Monograph Modernization Task Group (MMTG) has reviewed information available to us to identify several excipient monographs that we believe should be moved up in prioritization as candidates for modernization. These are listed alphabetically, below:

- Butylated Hydroxyanisole
- Butylated Hydroxytoluene
- Calcium Stearate
- Crosslinked Sodium Carboxymethylcellulose (Croscarmellose Sodium, Sodium CMC)
- Dextrose Excipient
- Gelatin
- Guar Gum
- Microcrystalline Cellulose (MCC)
- Pregelatinized Starch
- Shellac
- Silicon Dioxide (Colloidal)
- Titanium Dioxide

Our review of the USP-NF monograph test requirements for the most common pharmaceutical excipients (source: International Pharmaceutical Excipients Council of the Americas) revealed that these 12 excipients may be at elevated risk of adulteration due to a lack of specificity of the *Identification* test. FDA is especially concerned that the compendial tests for *Identification* be specific and rigorous, since under the current good manufacturing practice (CGMP) regulations, manufacturers of finished pharmaceuticals must perform at least one test to verify the identity of all component ingredients used to make the finished pharmaceutical product, and, where available, the compendial identity test is often used.

We note that several of the excipient monographs identified above do not appear on USP's list of priority monographs and request they be included.

Please feel free to contact Paul Seo at 301-796-4874 or Larry Ouderkirk at 301-796-1585 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  
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Larry Ouderkirk  
Co-Chair, Monograph Modernization Task Group  
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