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February 7, 2017

Also submitted electronically to <http://www.regulations.gov>

Division of Dockets Management (HFA-305) Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, Maryland 20852

Subject: Comments of List of Bulk Drug Substances That Can Be Used To Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug, and Cosmetic Act; Docket Number FDA-2016-N-3464

Dear Sir/Madam:

The United States Pharmacopeial Convention (USP) appreciates the opportunity to comment on the Food and Drug Administration's (FDA) issuance of the List of Bulk Drug Substances That Can Be Used To Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug, and Cosmetic Act.<sup>1</sup> USP also appreciates being a part of the development process of the 503A bulk list. USP looks forward to continuing to work in consultation with FDA and to participate with a representative member on the Pharmacy Compounding Advisory Committee.

USP is in agreement with the proposed criteria for evaluating bulk substances for inclusion on the 503A Bulks List. USP expressed this agreement in a meeting with FDA on March 28, 2016 and in a subsequent letter from Shawn Becker dated October 7, 2016. USP agrees with the addition of the identified bulk drug substances to the list as well as the substances considered and not proposed for inclusion on the 503A bulk list.

USP thanks you again for the opportunity to provide comments, and looks forward to continued successful collaboration and consultation. If you have questions or would like additional information regarding USP's comments, please contact Jeanne Sun, PharmD, Scientific Liaison, Healthcare Quality and Safety at [jhs@usp.org](mailto:jhs@usp.org) or (301) 230-3361.

Sincerely,

  
Jaap Venema, Ph.D.  
Executive Vice President and Chief Science Officer

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<sup>1</sup> Docket No. FDA-2016-N-3464: "List of Bulk Drug Substances That Can Be Used To Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug, and Cosmetic Act." Available at: <https://www.regulations.gov/docket?D=FDA-2016-N-3464> (accessed December 27, 2016)