General Chapter Prospectus: General Chapter <2740> Manufacturing Practices for Dietary Ingredients

Type of Posting: General Announcement
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Expert Committees: Botanical Dietary Supplements and Herbal Medicines (BDSHM) and Non-Botanical Dietary Supplements (NBDS)

Proposed New Title: Chapter <2740> *Manufacturing Practices for Dietary Ingredients*

Input Deadline: 15–Nov–2017

Estimated proposal PF: *Pharmacopeial Forum* 44(3) [May–June 2018]

Background and objective(s): USP is requesting early input from stakeholders on a newly proposed General Chapter <2740> *Manufacturing Practices for Dietary Ingredients*, which will be published for comment in *Pharmacopeial Forum* 44(3) [May–June 2018].

To enhance clarity in chapter <2750> *Manufacturing Practices for Dietary Supplements*, BDSHM and NBDS Expert Committees would like to propose a new chapter *Manufacturing Practices of Dietary Ingredients*. The current chapter <2750> covers both manufacturing practices for dietary supplements and dietary ingredients. The newly proposed General Chapter <2740> will be dedicated only to dietary ingredients, which will be separated from the current general chapter <2750> *Manufacturing Practices for Dietary Supplements*. The chapter <2750> will now cover only manufacturing practices for dietary supplements through a concurrent revision. The organizational structure of the new chapter will be similar to that of chapter <2750>. The chapter will incorporate additional details such as aspects of the recent Food Safety Modernization Act (FSMA) regulatory requirements for foods including dietary ingredients and requirements for a Hazard Analysis and Risk-based Preventive Controls (HARPC) plan per 21 CFR 117 Subpart C. Also, the chapter will include an additional requirement for FSMA supply chain controls per 21 CFR 117 Subpart G, additional details regarding requirements for FSMA Supply-Chain Program in 21 CFR 117 Subpart G, and Sanitary Transportation in 21 CFR 1 Subpart O.

Should you have any questions, please contact Seong Jae (SJ) Yoo, Scientific Liaison to BDSHM and NBDS Expert Committees (301–230–6366 or

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