Disintegration and Dissolution of Dietary Supplements

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Expert Committee: Dietary Supplements—Performance Standards

In accordance with the Rules and Procedures of the 2005–2010 Council of Experts, section 9.08(c)*, USP is postponing General Chapter <2040> Disintegration and Dissolution of Dietary Supplements, Dissolution Soft Gelatin Capsules official date to May 1, 2010.

*9.08(c) Granting of postponement. The Expert Committee responsible for approving the standard for which postponement is sought shall have the authority to postpone the official date of any requirement or textual material in such standards; provided, however, that all decisions to postpone shall require review and approval by the CoE Chairperson, who may at his or her option refer the matter to the Executive Committee for its consideration.

Affected Text

The General Chapter retains the following text to exempt soft gelatin capsules from the Dissolution requirements. ”Soft gelatin capsule preparations of dietary supplements meet the requirements for Disintegration.” The text indicates that soft gelatin capsules will meet the requirements for Disintegration rather than the requirements for Dissolution.

Background

The aforementioned sentence to exempt Dissolution requirements for soft gelatin capsules was included by Interim Revision Announcement (IRA) revision effective on January 1, 1995 following the conclusions of the USP Open Conference on Nutritional Supplements held in Cambridge Massachusetts in May 1994. USP intended to indicate that soft gelatin capsules will meet the requirements for Disintegration rather than the requirements for Dissolution. Concomitantly with the IRA revision, USP also stated that ”At a later date a revision may be proposed in PF to delete the sentence specifying that soft gelatin capsule preparations meet the requirements for Disintegration, and thereby implement the Dissolution requirements for all capsule preparations.”

The proposal to delete the sentence was published in PF 32(6) [Nov–Dec 2006]. No negative comments were received for the proposal and therefore the sentence was deleted from USP 31–NF 27, which became official on May 1, 2008. Industry representatives responded that many dietary supplements formulated in soft gelatin capsules would not comply with the change by the official date. Therefore, the Dietary Supplements-Performance Standards Expert Committee and the Chair of the Council of Experts approved postponing the official date of the Dissolution requirements to May 1, 2009.

USP received further industry response requesting an extension to permit time for validation testing of an alternative Dissolution test. The Dietary Supplements-Performance Standards Expert Committee and the Chair of the Council of Experts has approved a revised postponement to the Dissolution requirements with the new official date May 1, 2010.

Should you have any questions, please contact Gabriel Giancaspro, Director, Dietary Supplements (301-816-8343 or gig@usp.org).

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