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## Talc

**Type of Posting:** Revision Bulletin: POSTPONEMENT

**Posting Date:** 29–Apr–2011; updated 30–Jun–2011\*

**Official Date:** Postponed indefinitely

**Expert Committee:** Monographs—Excipients

**Reason for Revision:** Safety

Based on industry comments, and in accordance with the Rules and Procedures of the 2010–2015 Council of Experts, the Monographs—Excipients Expert Committee has indefinitely postponed the requirement to revise the Labeling section to indicate "that Talc is not derived from deposits that are known to contain associated asbestos." This statement was originally included in the Revision Bulletin posted on 29 April 2011.

Based on discussions with FDA, USP decided that the final language and placement of the proposed statement would be best handled by the Talc Expert Panel, which has been established to work on appropriate methods for determining absence of asbestos. In order to give the Expert Panel time to address this issue, and to avoid confusion in the industry, USP proposes the implementation of the Revision Bulletin for the labeling statement be postponed. The final language will be recommended by the Talc Expert Panel, and subsequently approved by the Monographs—Excipients Expert Committee.

The current *USP–NF* Talc monograph remains official until further notice. For inclusion into *USP 35–NF 30*, the original labeling language will remain and the revised labeling section will be marked as postponed indefinitely, pending the final decision of the Talc Expert Panel and Monographs—Excipients Expert Committee.

Should you have any questions, please contact Kevin Moore, Ph.D. (301-816-8369 or [ktm@usp.org](mailto:ktm@usp.org)).

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\*This posting on 30 June 2011 replaces the 29 April 2011 posting; only the 30 June 2011 posting is available. The 29 April 2011 posting introduced a revision to the Labeling section to assure that Talc is not sourced from mines that are known to contain asbestos, and indicated an official date of 01 August 2011. The purpose of this update is to indefinitely postpone that change.