## Salix Species Bark Family of monographs

Type of Posting: Notice of Intent to Revise

Posting Date: 18–May–2017

Official Date: 01–Aug–2017, Revision Bulletin and 01–Mar–2018, Interim Revision Announcement

Expert Committee: Botanical Dietary Supplements and Herbal Medicines

In accordance with section 7.04 (c) of the 2015–2020 Rules and Procedures of the Council of Experts, this is to provide notice that the Botanical Dietary Supplements and Herbal Medicines Expert Committee intends to revise the *Salix* Species family of monographs, including *Salix* Species Bark, *Salix* Species Bark Powder, and *Salix* Species Bark Dry Extract.

The Salix monographs were initially published for comment in *Pharmacopeial Forum* 42(1) [Jan.–Feb. 2016] and subsequently approved for inclusion in the *Second Supplement* to *USP 40–NF 35*, which will become official on December 1, 2017. Based on safety concerns the Botanical Dietary Supplements and Herbal Medicines Expert Committee has recommended the addition of the following labeling statement to the Salix Species family of monographs which were approved for publication in the *Second Supplement* to *USP 40–NF 35*: "**Dosage forms prepared with this article should bear the following statement: Not for use in children, women who are pregnant or nursing, or by persons with known sensitivity to aspirin."** 

It is anticipated that proposed Interim Revisions Announcements (IRAs) to the Salix species monographs will be published in *Pharmacopeial Forum* 43(5) [Sep.–Oct. 2017] pursuant to section 7.02 of the Rules and Procedures. The comment period for these revisions will end on November 30, 2017. Unless otherwise decided by the Botanical Dietary Supplements and Herbal Medicines Expert Committee based on comments received, the IRAs will be posted online on January 26, 2018 and will become official on March 1, 2018.

In addition, it is also anticipated that the Botanical Dietary Supplements and Herbal Medicines Expert Committee will postpone the official date of the Salix Species monographs via Revision Bulletins to be posted July 28, 2017 and become official December 1, 2017. The postponements will

remain in effect until the IRAs to be published in *Pharmacopeial Forum* 43(5) become official.

Should you have any questions, please contact Anton Bzhelyansky, Scientific Liaison to the Botanical Dietary Supplements and Herbal Medicines Expert Committee at (301-230-6303 or <u>anb@usp.org</u>).