Nicotine Polacrilex

Type of Posting: Notice of Intent to Revise

Posting Date: 10-Apr-2017

Targeted Official Date: 01–May–2017, Revision Bulletin (Postponement)

Expert Committee: Chemical Medicines Monographs 4

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 Chemical Medicines Monographs 4 Expert Committee intends to revise the Nicotine Polacrilex monograph.

Based on comments received, the Expert Committee proposes to postpone the deletion of the test for *Water Determination, Method I* <921> and to postpone the addition of the test for *Loss of Drying* <731> under the *Specific Tests* section, which were published in *USP 40–NF 35.*

The USP 40–NF 35 revision is scheduled to become official on May 1, 2017. It is anticipated that a Revision Bulletin to postpone these revisions will be posted on April 28, 2017 and become official on May 1, 2017.

A future revision to use a flexible monograph approach using different procedures to accommodate glycerin containing and glycerin free Nicotine Polacrilex is being considered. The process for and timing of this revision will be determined following additional consideration by the Expert Committee and USP staff.

Should you have questions, please contact Gerald Hsu, Ph.D., Senior Scientific Liaison to the Chemical Medicines Monograph 4 Expert Committee gdh@usp.org or 301-221-2097.

