Methylcobalamin and Methylcobalamin Tablets

Type of Posting: Notice of Intent to Revise

Posting Date: 31–Mar–2017

Targeted Official Date: 01-Aug-2018, In-Process Revision

Expert Committee: Non-Botanical Dietary Supplements

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 Non-Botanical Dietary Supplements Expert Committee intends to revise the Methylcobalamin and Methylcobalamin Tablets monograph.

The Expert Committee proposes to revise the aforementioned monographs to remove a Note about the handling of a USP Cyanocobalamin RS. To avoid changes related to different lots of reference standards, it is the USP policy to include details about the handling of reference standard only in reference standard labels and USP Certificates for the corresponding lot. USP is releasing a new pure crystalline form of USP Cyanocobalamin RS. Thus, it is proposed to delete the note indicating that the USP Cyanocobalamin RS is a mixture of cyanocobalamin and mannitol at 1%.

It is anticipated that the proposed revision will be published in Pharmacopeial Forum 43(3) [May–Jun. 2017] pursuant to section 7.02 of the Rules and Procedures. The comment period for this revision ends on July 31, 2017. In the absence of any adverse comments the proposed revision will be submitted to ballot for official adoption in the *First Supplement* to *USP 41-NF 46*, which will become official on August 1, 2018.

Should you have any questions, please contact Huy Dinh, Senior Scientific Liaison to the Non-Botanical Dietary Supplements Expert Committee (301-816-8594 or httd@usp.org).

