Omega-3-Acid Ethyl Esters

Type of Posting: Notice of Intent to Revise

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Expert Committee: Monographs—Dietary Supplements and Herbal Medicines Expert Committee

In accordance with section 7.05 (c) of the 2010–2015 Rules and Procedures of the Council of Experts, this is to provide notice that the Monographs—Dietary Supplements and Herbal Medicines Expert Committee, which is responsible for monographs applicable to naturally derived drug products and drug substances, intends to revise the Omega-3-Acid Ethyl Esters monograph via an Interim Revision Announcement (IRA).

The Expert Committee recently proposed revisions to the *Definition* and *Assay* sections of the Omega-3-Acid Ethyl Esters monograph based on the submissions and supporting data received from a manufacturer whose article is subject to the existing monograph (see General Notices section 5.40 *Identity*). These revisions were published for public comment in Pharmacopeial Forum 40(5) [Sep.–Oct. 2014].

As a result of the public comments received, the Expert Committee has proposed additional revisions to the Omega-3-Acid Ethyl Esters monograph, which include the following:

- The *Definition* section is revised by removing some of the statements related to acceptance criteria and purification processes because ingredients obtained through more than one purification process are now permitted in the monograph.
- A new *Identification* test to distinguish the approved APIs from other non-approved lower concentrations of omega-3-acid ethyl esters is added. The new test is also linked to a labeling requirement to identify the type of omega-3-acid ethyl esters contained in the drug products as type A.
- The *Assay* acceptance criteria is revised by adding a new column titled Acceptance criteria II in Table 1, for articles labeled as containing Omega-3-Acid Ethyl Esters of the type A.

- A labeling requirement is added to the *Labeling* section to indicate whether the article contains Omega-3-Acid Ethyl Esters of the type A.
- The *Impurity* test for the limit of lead, arsenic, cadmium, and mercury in the revised monograph is retained until the implementation of General Chapter <232> *Elemental Impurities—Limits*.

It is anticipated that the revision will be published as a proposed IRA in Pharmacopeial Forum 41(3) [May–Jun. 2015] with a comment deadline of July 31, 2015. If approved by the Expert Committee, the IRA will be published on USP's website on September 25, 2015 and become official on November 1, 2015.

Should you have any questions, please contact Huy Dinh, Senior Scientific Liaison to the Monographs—Dietary Supplements and Herbal Medicines Expert Committee (301–816–8594 or htd@usp.org).