Omega-3-Acid Ethyl Esters Capsules

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 Capsules 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 Capsules 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].

Based on the public comments received to the proposed revision published in *PF* 40(5), the Expert Committee has proposed additional revisions to the monograph, which include the following:

- A new *Identification* test to distinguish the Capsule's content with APIs that contain different concentrations of Omega-3-Acid Ethyl Esters with reference to *Acceptance criteria* under the *Specific tests*, *Concentration of Omega-3-Acid Ethyl Esters* is added.
- A *Concentration of Omega-3-Acid Ethyl Esters* test in the *Specific tests* section is added. The *Acceptance criteria* for this test will include *Acceptance criteria I*, for APIs having NLT 90% (w/w) of total omega-3-acid ethyl esters, and *Acceptance criteria II*, for APIs having NLT 78% (w/w) of total omega-3-acid ethyl esters, which is intended for capsules labeled as containing Omega-3-Acid Ethyl Esters of the type A.
- A requirement to the *Labeling* section is added to indicate whether the capsules contain Omega-3-Acid Ethyl Esters of the type A.

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 Natalia Davydova, Scientific Liaison to the Monographs—Dietary Supplements and Herbal Medicines Expert Committee (301–816–8328 or nd@usp.org).