Insulin Glargine Injection

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Expert Committee: Biologics Monographs 1—Peptides

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 Biologics Monographs 1—Peptides Expert Committee intends to revise the Insulin Glargine and Insulin Glargine Injection.

Based on the comments with supporting data were received, the Expert Committee proposes to revise the Insulin Glargine Injection as follows to reflect the FDA-approved specification.

- Revise the acceptance criteria for *Zinc determination* from 27.0 – 33.0 µg/mL to 20 – 40 µg/mL
- Widen the limit of high molecular weight proteins from NMT 0.3% to 0.5%

In addition, the Expert Committee also intends to revise the titles of the *Impurities* and *Related Proteins* sections to *Product-Related Substances and Impurities* and *Product-Related Substances respectively*. Subsequently, the term “related substance” was replaced with the term “related protein.”

It is anticipated that the proposed revision will be published as an Interim Revision Announcement (IRA) in Pharmacopeial Forum 42(3) [May–Jun. 2016] pursuant to section 7.02 of the Rules and Procedures. The comment period for this revision ends on July, 31, 2016. In the absence of any adverse comments the proposed IRA will become official on November 1, 2016.

Should you have any questions, please contact Edith Chang (301-816-8392 or yec@usp.org).