Corticotropin Injection, Corticotropin for Injection, Repository Corticotropin Injection

Type of Posting: Notice of Intent to Revise

Posting Date: 18-Dec-2015

Targeted Official Date: Interim Revision Announcement; 1-July-2016

Archive Date: 24-Jun-2016

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 intends to revise the Corticotropin Injection, Corticotropin for Injection, Repository Corticotropin Injection monographs.

Comments were received that indicate ether is no longer used as an anesthetic agent in the standard practices because ether is highly flammable and volatile, which are safety and hazard concerns to the users. The Expert Committee proposes to revise these three monographs to remove the use of ether to anesthetize the rats in the *Assay* section.

It is anticipated that the proposed revision will be published as an Interim Revision Announcement (IRA) in Pharmacopeial Forum 42(1) [Jan.—Feb. 2016] pursuant to section 7.02 of the Rules and Procedures. The comment period for this revision ends on March 30, 2016. In the absence of any adverse comments the proposed IRA will become official on July 1, 2016.

Should you have any questions, please contact Edith Chang (301-816-8391 or yec@usp.org).

