Cefdinir for Oral Suspension

Type of Posting: Notice of Intent to Revise

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Expert Committee: Monographs—Small Molecules 1

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 USP Monographs—Small Molecules 1 Expert Committee intends to revise the Cefdinir for Oral Suspension monograph as follows:

1. The limit of E-Cefdinir is widened from 1.2 to 1.4 based on FDA-approved specifications.
2. The relative response factors are revised to be consistent with the validation data.
3. The reporting threshold is revised to 0.1%, which is consistent with the International Council of Harmonization (ICH) guidelines for drug products with a maximum daily dose less than 1 g.

It is anticipated that the revision will be published as a Proposed Interim Revision Announcement in PF 40(2) [Mar–Apr 2014] pursuant to section 7.02 of the Rules and Procedures. The comment period for this revision ends on May 31, 2014.

Should you have any questions, please contact Ahalya Wise, M.S. (301–816–8161 or aww@usp.org).