



Commentary

PF 45(3),

Comments were received for the following when they were proposed in Pharmacopeial Forum:

Monographs:

Formoterol Fumarate

Monograph/Sections: Formoterol Fumarate / Multiple sections

Expert Committee: Chemical Medicines Monographs 4

No. of Commenters: 2

Comment #1: The commenter requested revising the *Resolution* requirement between formoterol related compound C and formoterol related compound D within the test for *Organic Impurities* from “NLT 1.5” to “NLT 1.0”.

EC Response: Comment not incorporated. The Expert Committee will consider future revisions to the monograph upon receipt of the necessary supporting data.

Comment #2: The commenter requested removing the ‘reporting threshold’ from the test for *Organic Impurities* as the appropriate value will vary based on product-specific factors that should be addressed as an application assessment issue.

EC Response: Comment not incorporated. A general position regarding the inclusion or absence of reporting thresholds in monographs is still under discussion. The Expert Committee will consider future revisions to the monograph upon the outcome of these discussions.

EC-Initiated Change #1: The chemical names associated with USP Formoterol Related Compound C RS and USP Formoterol Related Compound D RS within the *USP Reference Standards* section are updated for consistency with current nomenclature conventions.