
Monographs and General Chapters Affected by Revision to General Chapter <601> AEROSOLS, NASAL SPRAYS, METERED-DOSE INHALERS, AND DRY POWDER INHALERS

Type of Posting: Notice of Intent to Revise

Posting Date: 25–Apr–2014

Targeted Official Date: TBD

Expert Committee: TBD

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 USP and its Expert Committees, as applicable, intend to revise multiple monographs and General Chapters in response to the revision of General Chapter <601> Aerosols, Nasal Sprays, Metered-Dose Inhalers, and Dry Powder Inhalers.

General Chapter <601> was revised and published in Supplement 1 to *USP 37–NF 32* with the new title “<601> Inhalation and Nasal Drug Products: Aerosols, Sprays, and Powders—Performance Quality Tests,” and will become official on August 1, 2014. This publication reflected several other revisions to the General Chapter to address stakeholder comments and was accompanied by the publication of new General Chapters <602> Propellants, <603> Topical Aerosols, and <604> Leak Rate, containing provisions previously addressed solely in <601>. USP has identified the following monographs and general chapters that reference General Chapter <601> and thus require some degree of revision to assure the appropriate General Chapter is referenced:

- <603> Topical Aerosols
- <1059> Excipient Performance
- <1151> Pharmaceutical Dosage Forms
- <1160> Pharmaceutical Calculations in Prescription Compounding
- <1601> Products for Nebulization—Characterization Tests

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- Bacitracin and Polymyxin B Sulfate Topical Aerosol
 - Benzocaine and Menthol Topical Aerosol
 - Benzocaine Topical Aerosol
 - Benzocaine, Butamben, and Tetracaine Hydrochloride Topical Aerosol
 - Betamethasone Dipropionate Topical Aerosol
 - Dexamethasone Sodium Phosphate Inhalation Aerosol
 - Dexamethasone Topical Aerosol
 - Dichlorodifluoromethane
 - Dichlorotetrafluoroethane
 - Epinephrine Bitartrate Inhalation Aerosol
 - Epinephrine Inhalation Aerosol
 - Ergotamine Tartrate Inhalation Aerosol
 - Fluticasone Propionate Inhalation Aerosol
 - Fluticasone Propionate Inhalation Powder
 - Isobutane
 - Isoetharine Mesylate Inhalation Aerosol
 - Isoproterenol Hydrochloride and Phenylephrine Bitartrate Inhalation Aerosol
 - Isoproterenol Hydrochloride Inhalation Aerosol
 - Isoproterenol Sulfate Inhalation Aerosol
 - Lidocaine Topical Aerosol
 - Metaproterenol Sulfate Inhalation Aerosol
 - Polymyxin B Sulfate and Bacitracin Zinc Topical Aerosol
 - Povidone-Iodine Topical Aerosol
 - Terbutaline Sulfate Inhalation Aerosol
 - Thimerosal Topical Aerosol
 - Tolnaftate Topical Aerosol
 - Triamcinolone Acetonide Topical Aerosol
 - Trichloromonofluoromethane

The process and timing for revisions to these monographs and general chapters will be determined following a careful analysis of the effects of the revision to General Chapter <601> and implementation of General Chapters <602>, <603>, and <604>. USP will post additional information as it becomes available. In the meantime, interested parties are encouraged to alert USP staff to any other effects they may recognize related to the revision of General Chapter <601>.

Should you have any questions or comments, please contact Kahkashan Zaidi, Ph.D., Principal Scientific Liaison (301-816-8269 or kxz@usp.org).