RE: USP Crystallized Trypsin Reference Standard and Associated Monographs

The purpose of this notice is to inform you that USP Trypsin Crystallized Reference Standard (RS) Catalog #1700002 is being discontinued. There are no intentions on developing a new lot of this RS. It is being removed from its associated USP compendial monographs and has been replaced with USP Trypsin Bovine RS Catalog #1699956 and USP Trypsin Recombinant Porcine RS Catalog #1700013.

The USP Trypsin Bovine RS and USP Trypsin Recombinant Porcine RS should not be used in tests specifying the use of the USP Crystallized Trypsin RS. They are only suitable for use in tests specifying the use of USP Trypsin Bovine RS or USP Trypsin Recombinant Porcine RS. Refer to the USP Certificates of the current lot of each RS for available values appropriate for their intended uses.

Please see the below details regarding the associated monographs:

USP Crystallized Trypsin Monograph

- Proposed revisions were published in Pharmacopeial Forum (PF) 43(6) and will become official on December 01, 2020. (https://www.uspnf.com/pharmacopeial-forum)
  - The Briefing explains that the monograph name is being changed to “Trypsin” because crystallization is not the only way to purify trypsin from pancreas. The chemical information for both bovine and porcine trypsin will be included in the monograph.
  - The definition of the Trypsin Unit has been updated due to a change in the substrate in the Assay from BAEE to carboxbenzoxyl-valyl-glycyl-arginine-4-nitril-anilide acetate.
  - USP Trypsin Crystallized RS has been removed from the monograph.
  - USP Trypsin Bovine RS and USP Trypsin Recombinant Porcine RS have been added to the monograph.

USP Chymotrypsin and Chymotrypsin for Ophthalmic Solution Monographs

- Proposed revisions were published in Pharmacopeial Forum (PF) 46(3) and are targeted to become official on December 01, 2021. (https://www.uspnf.com/pharmacopeial-forum)
- USP Trypsin Crystallized RS has been removed from the monograph.
- USP Trypsin Bovine RS has been added to the monograph.

USP Aprotinin and Aprotinin Injection Monographs

- USP plans to omit these Aprotinin monographs. A Notice of Intent to Revise is posted at https://www.uspnf.com/notices.
- It is anticipated that the proposed omissions will be published in Pharmacopeial Forum (PF) 46(5) [Sept2020] and are targeted to become official on May 1, 2022.

IMPORTANT: Existing orders of USP Trypsin Crystallized RS Catalog #1700002 awaiting fulfillment will be canceled by USP. USP cannot automatically fulfill previously placed orders of Catalog #1700002 with another catalog item. To place a new order for the currently available USP Reference Standards, please go to the online USP store at https://store.usp.org or contact Customer Service at custsvc@usp.org.

For technical questions, please contact Reference Standard Technical Services at rstech@usp.org.