RE: USP Enoxaparin Sodium Monograph and USP Enoxaparin Sodium Molecular Weight Calibrant A and B Reference Standards Update

The purpose of this notice is to inform you that USP Enoxaparin Sodium Molecular Weight Calibrant A Reference Standard (RS) catalog #1235853 and USP Enoxaparin Sodium Molecular Weight Calibrant B Reference Standard (RS) catalog #1235864 will be discontinued due to upcoming revisions to the official USP compendial use for these products. Both Reference Standards were previously developed for use in the Molecular Weight Distribution and Weight-Average Molecular Weight test of the USP Enoxaparin Sodium Monograph. The test will be replaced with the use of General Chapter <209> Low Molecular Weight Heparin Molecular Weight Determinations. General Chapter <209> does not require the use of USP Enoxaparin Sodium Molecular Weight Calibrant A RS or USP Enoxaparin Sodium Molecular Weight Calibrant B RS.

The proposed revision to the USP Enoxaparin Sodium Monograph was posted in PF 48(3) on May 02, 2022. The proposal was approved and implemented via an Interim Revision Announcement (IRA) published in the USP-NF Online on November 18, 2022 with a delayed official date of December 01, 2023. Early adoption (prior to the official date) has been allowed as per General Notices and Requirements “3.10. Applicability of Standards.”

The stock of USP Enoxaparin Sodium Molecular Weight Calibrant A RS catalog #1235853 Lot R06720 has been depleted, and the lot has been assigned a Valid Use Date of November 30, 2023. It will remain suitable for use in the currently official version of the USP Enoxaparin Sodium Monograph where the use of USP Enoxaparin Sodium Molecular Weight Calibrant A RS is specified through its assigned Valid Use Date. USP will not release a new lot of this RS as it will be discontinued due to the above monograph revision.

The stock of USP Enoxaparin Sodium Molecular Weight Calibrant B RS catalog #1235864 Current Lot R06710 is expected to deplete soon. Upon depletion, it will be assigned a Valid Use Date about twelve months from the date of depletion. It will remain suitable for use in the currently official version of the USP Enoxaparin Sodium Monograph where the use of USP Enoxaparin Sodium Molecular Weight Calibrant B RS is specified through its assigned Valid Use Date. USP will not release a new lot of this RS as it will be discontinued due to the above monograph revision.

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