The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.

On July 30, 2024, VBI Vaccines Inc. (VBI) and certain of its subsidiaries initiated restructuring proceedings under the Companies' Creditor Arrangement Act in Ontario, Canada ("CCAA"), and under Chapter 15 of the U.S. Bankruptcy Code. As part of these proceedings, Ernst & Young Inc. ("EY") was appointed by the courts as the monitor during the restructuring, and a sale and investment solicitation process commenced in early August to identify one or multiple purchasers of VBI's assets on an efficient basis. VBI's original plan was to find a purchaser for PreHevbrio [Hepatitis B Vaccine (Recombinant)], such that we could transfer the BLA, and the vaccine could remain on the U.S. market. Unfortunately, we
and EY were unable to do so.

As a result, VBI formally notified the FDA on October 25, 2024 of its permanent discontinuance in manufacturing, and withdrawal from the U.S. market, of PreHevbrio (**NDC 75052-001-01, 75052-001-10**), as VBI is no longer in a financial position to support the systems and personnel needed to maintain responsibility for various regulatory matters, such as those relating to product recalls, quality complaints, pharmacovigilance system and oversight, and the pregnancy registry associated with PreHevbrio. VBI is asking for your support in the immediate suspension of any dispensing and use of the product and proper disposal of any inventory according to local regulatory requirements.

PRODUCT: PreHevbrio

NDC NUMBERS: 75052-001-01, 75052-001-10