August 21, 2020

Division of Dockets Management
Food and Drug Administration (HFA-305)
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Suitability Petition

Dear Sir or Madam:

The Weinberg Group LLC, a ProPharma Group Company ("Petitioner") submits this Suitability Petition, pursuant to Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") and in accordance with 21 C.F.R. § 314.93 and 21 C.F.R. § 10.20 and 21 C.F.R. § 10.30, to request that the Commissioner of the U.S. Food and Drug Administration ("FDA") declare that the drug products, Vasopressin Injection USP, in strengths of 50 units/2.5 mL (2.5 mL/vial in a single dose vial) and 100 units/5 mL (5 mL/vial in a single dose vial), are suitable for consideration in an Abbreviated New Drug Application ("ANDA").

A. Actions Requested

The petitioner requests that the FDA declare that the drug products, Vasopressin Injection USP, 50 units/2.5 mL (2.5 mL/vial in a single dose vial) and 100 units/5 mL (5 mL/vial in a single dose vial), are suitable for submission as an ANDA.

The reference listed drug (RLD) product upon which this petition is based is Par Sterile Products LLC's Vasostrict® (Vasopressin Injection USP), 20 Units/mL (single-dose vial), New Drug Application ("NDA") 204485. Vasostrict® (Vasopressin Injection USP), 20 Units/mL (single-dose vial) is listed in the current edition of "Approved Drug Products with Therapeutic Equivalence Evaluations" ("Orange Book"). A copy of the entry for Vasostrict® (Vasopressin Injection USP), 20 Units/mL (single-dose vial), NDA 204485, from the current electronic edition of the Orange Book is included as Attachment 1.

Petitioner requests the FDA to declare that the drug products, Vasopressin Injection USP, 50 units/2.5 mL (2.5 mL/vial in a single dose vial) and 100 units/5 mL (5 mL/vial in a single dose

vial), which are two additional strengths of the RLD, are suitable for submission in an ANDA. Please note that this is only a change in total drug content and not concentration.

B. Statement of Grounds

FDC Act § 505(j)(2)(A)(iii) permits the submission of an ANDA for a drug product that differs in strength from that of the listed drug product provided that the FDA has first approved a petition permitting submission of such an application. Vasostrict® (Vasopressin Injection USP), 20 Units/mL (single-dose vial), the RLD for the proposed drug products, is indicated to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines. A copy of the most recent FDA-approved labeling for Vasostrict® is included as Attachment 2. The approved labeling provides the following recommended dilution information in the **DOSAGE AND ADMINISTRATION** section:

2 DOSAGE AND ADMINISTRATION

2.1 Preparation of Diluted Solutions

Dilute Vasostrict® in normal saline (0.9% sodium chloride) or 5% dextrose in water (D5W) prior to use for intravenous administration. Discard unused diluted solution after 18 hours at room temperature or 24 hours under refrigeration.

Table 1 Preparation of diluted solutions

Fluid restriction?	Final concentration	Mix	
		Vasostrict®	Diluent
No	0.1 units/mL	2.5 mL (50 units)	500 mL
Yes	1 unit/mL	5 mL (100 units)	100 mL

Inspect parenteral drug products for particulate matter and discoloration prior to use, whenever solution and container permit.

Petitioner is developing two additional strengths, 50 units/2.5 mL (2.5 mL/vial in a single dose vial) and 100 units/5 mL (5 mL/vial in a single dose vial). Essentially, the two new strengths contain the same units/mL of Vasopressin as that of Vasostrict® (Vasopressin Injection USP), 20 units/mL (1 mL), i.e., 20 units/mL, with the fill volume increased to 2.5 mL/vial and 5 mL/vial, respectively.

As is evident from the above table, to prepare a final concentration of 0.1 units/mL, only one vial of the proposed new strength (same concentration as the RLD) 2.5 mL vial (50 units/

2.5 mL) will be needed instead of two and a half vials of the currently approved strength of 1 mL (20 units/mL). Similarly, for the preparation of 1 unit/mL final concentration, only one vial of the proposed new strength (same concentration as the RLD) 5 mL (100 units/5 mL) will be needed instead of five vials of the currently approved strength of 1 mL (20 units/mL). After diluting the proposed drug products with the recommended diluent, the final solution will have the same concentration as the RLD diluted solution.

The proposed drug products, which differ in strengths and presentations from the RLD, do not pose questions of safety or effectiveness. The active ingredient, indication, route of administration, intended patient population, warnings and recommendations for use of the proposed drug products are the same as that of the RLD. Draft labeling for the proposed drug products, Vasopressin Injection USP, 50 units/2.5 mL (2.5 mL/vial in a single dose vial) and 100 units/5 mL (5 mL/vial in a single dose vial) are provided as Attachment 3. The labeling of the proposed product will be identical to the RLD with the exception of obvious changes in strengths sought in this petition and manufacturer-specific information. The proposed products would differ only in strength (total drug content) from the marketed Vasostrict® (Vasopressin Injection USP), 20 Units/mL (single-dose vial), approved under NDA 204485. The labeling of the proposed drug products is consistent with the RLD labeling in various respects:

- First, introduction of these two new strengths and presentations would provide practitioners with a convenient option for dosing without using multiple vials.
- Second, it provides for safer handling for drug preparation and administration, as fewer vials need to be combined for reconstitution leading to fewer preparation errors.
- Third, fewer drug preparations will help in minimizing potential microbial issues caused due to handling of multiple vials.

The Pediatric Research Equity Act ("PREA"), enacted in December 2003, amended the FD&C Act by requiring certain applications for a drug submitted under FD&C Act § 505 to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is deferred or waived. See FD&C Act § 505B(a)(I)(A)(i). Specifically, PREA applies to all applications for a new active ingredient, dosage form, indication, route of administration, or dosing regimen. See id. ANDAs submitted under an approved suitability petition for a change in strength are not subject to PREA requirements. See FDA, Draft Guidance for Industry, How to

Comply with the Pediatric Research Equity Act, 4 (Sep. 2005). Petitioner asserts that PREA is not applicable to the proposed drug products, Vasopressin Injection USP, 50 units/2.5 mL (2.5 mL/vial in a single dose vial) and 100 units/5 mL (5 mL/vial in a single dose vial), because the proposed change concerns new strengths. As such PREA should not serve as an impediment to the Agency granting this petition.

C. Environment Impact

The petitioner claims a categorical exclusion under 21 C.F.R. § 25.31 (a) from the requirement to submit an environment assessment.

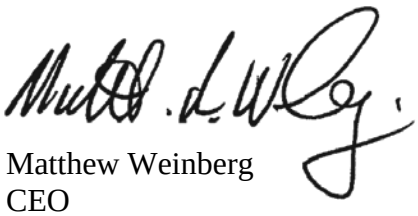
D. Economic Impact Statement

The petitioner will, upon request by the Commissioner, submit economic impact information, in accordance with 21 C.F.R. § 10.30(b).

E. Certification

The petitioner certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

Sincerely,



Matthew Weinberg
CEO
The Weinberg Group LLC

MRW/al

Atts.