August 20, 2019

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

Subject: ANDA suitability petition

Requesting the agency to permit for submission of ANDA for vasopressin injection 20 units per mL (10 mL fill volume) according to the discontinued formulation of Reference Listed Drug (RLD) NDA# 204485 Vasostrict® (vasopressin) Injection, 20 units/mL (1 mL fill) that was deemed acceptable for ANDA submission per agency's response to HPM petition FDA-2017-P-1096.

Dear Sir/ Madam,

The undersigned submits this petition on behalf of Aurobindo Pharma Ltd (APL). pursuant to Section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act and in accordance with 21 CFR §10.20 and §10.30 requesting the Commissioner of the Food and Drug Administration to permit for submission of ANDA for vasopressin injection 20 units per mL (10 mL fill volume) according to the discontinued formulation of RLD NDA# 204485 Vasostrict® (vasopressin) Injection, 20 units/mL (1 mL fill) that was deemed acceptable for ANDA submission per agency's response to HPM petition FDA-2017-P-1096.

A. Action Requested

The petitioner requests the Commissioner of the Food and Drug Administration to permit for submission of ANDA for vasopressin injection 20 units per mL (10 mL fill volume) according to the discontinued formulation of RLD NDA# 204485 Vasostrict® (vasopressin) Injection, 20 units/mL (1 mL fill) that was deemed acceptable for ANDA submission per agency's response to HPM petition FDA-2017-P-1096. The petitioner is requesting that the total drug content for this injectable product be increased to 200 units/10 mL (20 units/mL) from 20 units/mL (1 mL fill). The concentration of the solution will remain unchanged as 20 units/mL.

B. Statement of Grounds

Section 505(j)(2)(c) of the Federal Food, Drug and Cosmetic Act provides for the submission of an ANDA for a drug product that differs in strength (or in this case a parenteral drug product, total drug content) from that of the RLD provided the FDA has approved a petition that proposes filing such an application.

Vasostrict (vasopressin) Injection was originally approved for 1 mL MDV presentation on April 17, 2014. The formulation contains "*Chlorobutanol* and *Acetic Acid*" as excipients. Please refer to Original RLD package insert.

Later, the formulation of Vasostrict (vasopressin) Injection was revised in 2015, by removing "*chlorobutanol*" and replacing *Acetic Acid* with *Sodium Acetate*.

Subsequently, "Par Steriles" introduced 10 mL MDV presentation based on original 1 mL MDV formulation in which *Acetic Acid* (*present in original RLD formulation*) was replaced with *Sodium Acetate*. Please refer to current RLD package insert.

Per agency's response to HPM petition FDA-2017-P-1096, FDA determined that the original Vasostrict, 20 units per mL, formulation was not discontinued from sale for reasons of safety or effectiveness and also determined that FDA may accept and approve ANDAs that refer to Vasostrict as the RLD and propose to duplicate the original formulation of Vasostrict, 20 units per mL, if all other applicable requirements are met.

Now, APL intends to submit an ANDA for vasopressin injection 20 units per mL (10 mL fill volume) according to the discontinued formulation of RLD NDA# 204485 Vasostrict® (vasopressin) Injection, 20 units/mL (1 mL fill).

A comparison of the discontinued formulation of RLD and proposed generic drug product are tabulated below.

Attribute	**NDA# 204485; Vasostrict (vasopressin) Injection - Discontinued Formulation**	**Proposed Drug Product**	**Comparison**
Name	Vasopressin Injection, USP	Vasopressin Injection, USP	Same
Strength	20 units/mL	200 units/10 mL (20 units/mL)	The concentration of the solution will remain unchanged as 20 units/mL
Total drug content	20 units	200 units	
Volume	1 mL	10 mL	
Dosage Form	Injection	Injection	Same
Route of Administration	Intravenous	Intravenous	Same
Active Ingredient	Vasopressin – 20 units/mL	Vasopressin – 20 units/mL	Same
Inactive Ingredients	Chlorobutanol – 5 mg/mL	Chlorobutanol – 5 mg/mL	Same
	Acetic Acid - Q.s to adjust pH	Acetic Acid - Q.s to adjust pH	Same
	Water for Injection – Q.S	Water for Injection – Q.S	Same
Conditions of Use (Indications)	Indicated to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines.	Indicated to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines.	Same
Package Type Term	Multiple Dose Vial	Multiple Dose Vial	Same

The proposed 10 mL MDV formulation is in-line with 1 mL MDV formulation of original RLD except change in fill volume.

The proposed formulation does not pose concerns of safety or efficacy because the unit composition, the uses, the doses, and the route of administration are the same as those of the *original RLD* in view-of acceptability of original RLD formulation per above petition response.

The proposed generic drug product is intended for use only as described in the *Indications* and *Dosage and Administration* sections of the approved labeling of the RLD. The labeling for the proposed drug shall be identical to that of Par sterile's Vasostrict (vasopressin) Injection.

C. Environmental Impact

Issuance, amendment, or revocation of procedures for submission of applications for product development, testing and investigational use, and approval are categorically excluded from the requirements of an environmental assessment or impact statement under 21 CFR § 25.30(h).

D. Economic Impact

Information regarding economic impact will be submitted upon request by the commissioner.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all the 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.

Please contact the undersigned at AuroMedics Pharma LLC, 279 Princeton-Hightstown Rd. East Windsor, NJ 08520, USA, Tel: 609-642-1136, Cell: 267-474-4516, Fax: 732-917-0780, e-mail: vandolina@aurobindousa.com; if you have any questions regarding this submission.

Sincerely,

Sravani Ravipati

Digitally signed by Sravani Ravipati
DN: cn=Sravani Ravipati, o=AuroMedics Pharma LLC, ou=Senior Associate, Regulatory Affairs, email=sravipati@aurobindousa.com, c=US
Date: 2019.08.20 10:26:53 -04'00'

For Vincent P. Andolina (U.S. Agent for Aurobindo Pharma Limited)
Vice President, Regulatory Affairs
AuroMedics Pharma LLC