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November 18, 2019

BY ELECTRONIC SUBMISSION

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

Citizen Petition

The undersigned ("Petitioner") submits this Citizen Petition pursuant to the Federal Food, Drug, and Cosmetic Act ("FDC Act") and in accordance with 21 C.F.R. §§ 10.25(a) and 10.30 with regard to the FDA-designated Reference Standard ("RS") for Polymyxin B Sulfate Injection, Eq 500,000 units base/vial. The current RS, approved under Abbreviated New Drug Application ("ANDA") 060716, is commercially unavailable. For this reason, Petitioner requests that the Food and Drug Administration ("FDA") take action to maintain a pathway for ANDA submissions. Petitioner requests that FDA designate an additional (or new) RS for Polymyxin B Sulfate Injection, EQ 500,000 units base/vial, and amend the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") to reflect ANDA 202766 as a RS for the drug.

I. ACTION REQUESTED

Petitioner requests that FDA designate ANDA 202766 (Polymyxin B Sulfate Injection, EQ 500,000 units base/vial) held by Xellia Pharmaceuticals APS as a RS for purposes of FDA evaluation of ANDAs for Polymyxin B Sulfate Injection, EQ 500,000 units base/vial.

II. STATEMENT OF GROUNDS

FDC Act § 505(j) allows the marketing of generic versions of previously approved drug products based on FDA approval of an ANDA. To obtain ANDA approval, the applicant must show, among other things, that with respect to a listed drug (i.e., a previously approved drug product), the generic drug product has the same active ingredient(s) in the

same strength, dosage form and route of administration, has essentially identical labeling, and is bioequivalent.

A "listed drug" includes a new drug product that has an effective approval under FDC Act § 505(j), that has not been withdrawn or suspended under FDC Act §§ 505(e)(1) through (5) or (j)(5), and that has not been withdrawn from sale for reasons of safety or effectiveness. See 21 C.F.R. § 314.3. Listed drugs are identified in FDA's Orange Book. An RLD is the listed drug identified by FDA as the drug product on which an ANDA applicant should rely in seeking approval of an application. The product designated by FDA as the "reference standard," in the Orange Book, must be used to conduct the in vivo bioequivalence testing required for FDA approval. However, where there is a "limited or no quantities of the reference standard in distribution" a potential ANDA applicant may request designation of a new RS through the submission of a citizen petition. FDA, *Draft Guidance for Industry, Referencing Approved Drug Products in ANDA Submissions*, at 9 (Jan. 2017).

Despite diligent efforts to obtain sufficient quantities of the present RS—Polymyxin B Sulfate Injection, EQ 500,000 units base/vial (ANDA 060716)—the drug product is not commercially available and appears to have been discontinued from marketing. Indeed, it is not even listed for sale on the West-Ward Pharms. (now known as Hikma) website. As such, Polymyxin B Sulfate Injection, EQ 500,000 units base/vial, is shielded from additional generic competition. In an effort to introduce further competition, FDA should designate one of the following ANDAs (other than (ANDA 060716) listed in the Orange Book as the new (or an additional) RS for Polymyxin B Sulfate Injection, EQ 500,000 units base/vial, and preferably ANDA 202766.

POLYMYXIN B SULFATE

INJECTABLE;INJECTION

POLYMYXIN B SULFATE

AP		AUROBINDO PHARMA LTD	EQ 500,000 UNITS BASE/VIAL	A206589	001	Apr 04, 2016
AP		FRESENIUS KABI USA	EQ 500,000 UNITS BASE/VIAL	A065372	001	Jan 10, 2008
AP		GLAND PHARMA LTD	EQ 500,000 UNITS BASE/VIAL	A207322	001	Apr 14, 2016
AP		MYLAN ASI	EQ 500,000 UNITS BASE/VIAL	A090110	001	Jun 29, 2011
AP	‡	WEST-WARD PHARMS INT	EQ 500,000 UNITS BASE/VIAL	A060716	001	
AP		X GEN PHARMS	EQ 500,000 UNITS BASE/VIAL	A063000	001	Sep 30, 1994
AP		XELLIA PHARMS APS	EQ 500,000 UNITS BASE/VIAL	A202766	001	Jan 15, 2014

There is a sound basis for selecting an ANDA—and preferably ANDA 202766—as a new RS. We have been assured that Polymyxin B Sulfate Injection, EQ 500,000 units base/vial, held by Xellia Pharmaceuticals APS (ANDA 202766), is readily accessible. It is therefore a suitable candidate for RS designation.

Accordingly, the undersigned requests that FDA designate in the Orange Book Polymyxin B Sulfate Injection, EQ 500,000 units base/vial, approved under one of the above-cited ANDAs (and, in particular, ANDA 202766) as a new RS.

III. ENVIRONMENTAL IMPACT

An environmental assessment report on the action requested in this petition is not required under 21 C.F.R. § 25.31.

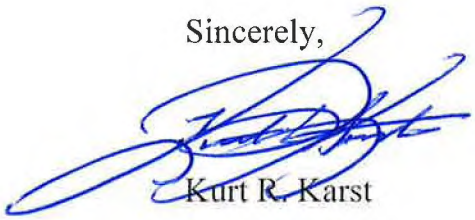
IV. ECONOMIC IMPACT

In accordance with 21 C.F.R. § 10.30(b), economic impact information is to be submitted only when requested by the Commissioner following review of the petition. Petitioner hereby commits to promptly provide this information, if so requested.

V. CERTIFICATION

Petitioner certifies that, to the best knowledge and belief of Petitioner, 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 is unfavorable to the petition.

Sincerely,



Kurt R. Karst