LAW OFFICES
HYMAN, PHELPS & MCNAMARA, P.C.

700 THIRTEENTH STREET, N.W.
SUITE 1200
WASHINGTON, D.C. 20005-5929
(202) 737-5600

FACSIMILE
(202) 737-9329

www.hpm.com

KURT R. KARST

Direct Dial (202) 737-7544
kkarst@hpm.com

October 26, 2020

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 Nitrofurantoin Oral Suspension, 25 mg/5 mL. The current RS, approved under New Drug Application ("NDA") 009175, is commercially unavailable. For this reason, Petitioner requests that the Food and Drug Administration ("FDA") take action to maintain a pathway for Abbreviated NDA ("ANDA") submissions. Petitioner requests that FDA designate an additional (or new) RS for Nitrofurantoin Oral Suspension, 25 mg/5 mL, and amend the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") to reflect ANDA 201355 as a RS for the drug.

I. ACTION REQUESTED

Petitioner requests that FDA designate ANDA 201355 (Nitrofurantoin Oral Suspension, 25 mg/5 mL) held by Nostrum Laboratories Inc. as a RS for purposes of FDA evaluation of ANDAs for Nitrofurantoin Oral Suspension, 25 mg/5 mL. Petitioner further requests that FDA expedite a response to this petition so that bioequivalence studies can be conducted and an ANDA can be submitted to FDA.[1]

[1] This is the ***third citizen petition*** requesting that FDA designate a new RS for Nitrofurantoin Oral Suspension, 25 mg/5 mL. FDA was first petitioned in January 2018, *see* Citizen Petition, Macleods Pharmaceuticals Limited, Docket No. FDA-2018-P-0345 (Jan. 23, 2018), and then again in October 2019, *see* Citizen Petition, Lachman Consultant Services, Inc., Docket No. FDA-2019-P-4879 (Oct. 18, 2019). FDA has not substantively responded to either citizen petition.

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—FURADANTIN (nitrofurantoin) Oral Suspension, 25 mg/5mL (NDA 009175)—the drug product is not commercially available. As such, Nitrofurantoin Oral Suspension, 25 mg/5 mL, is shielded from additional generic competition. In an effort to introduce further competition, FDA should promptly designate ANDA 201355 as the new (or an additional) RS for Nitrofurantoin Oral Suspension, 25 mg/5 mL.

NITROFURANTOIN						
SUSPENSION;ORAL						
	FURADANTIN					
AB	+!	CASPER PHARMA LLC	25MG/5ML	N009175	001	
	NITROFURANTOIN					
AB		ACTAVIS MID ATLANTIC	25MG/5ML	A205180	001	May 03, 2016
AB		AMNEAL PHARMS	25MG/5ML	A201679	001	May 11, 2011
AB		NOSTRUM LABS INC	25MG/5ML	A201355	001	Aug 14, 2013
AB		NOVEL LABS INC	25MG/5ML	A201693	001	Sep 08, 2014

There is a sound basis for selecting an ANDA 201355 as a new RS. According to the American Society of Health-System Pharmacists ("ASHP"), as of October 15, 2020, the only available Nitrofurantoin Oral Suspension, 25 mg/5 mL, drug product on the market is product approved under ANDA 201355 (Attachment No. 1).

Accordingly, the undersigned requests that FDA designate in the Orange Book Nitrofurantoin Oral Suspension, 25 mg/5 mL, approved under ANDA 201355 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.

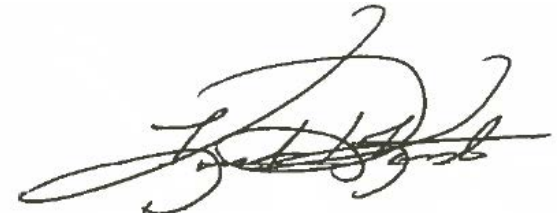
IV. ECONOMIC IMPACT

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