December 21, 2022

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

Dear Sir/Madam,

The undersigned, Lachman Consultant Services, Inc. (Lachman Consultants), respectfully submits this petition pursuant to the Federal Food, Drug and Cosmetic Act ("FDC Act") and in accordance with regulations at 21 C.F.R. §10.25(a), § 10.30, and 21 C.F.R. § 314.161, requesting the Commissioner of the Food and Drug Administration to provide a determination on whether a listed drug has been voluntarily withdrawn for safety or effectiveness reasons as outlined below.

A. Action Requested

The Petitioner requests that the Commissioner of the Food and Drug Administration determine whether the previously designated Reference Listed Drug (RLD), CHIROCAINE® (Levobupivacaine Injection, 2.5 mg(base)/mL, 10 mL and 30 mL vials, 5 mg(base)/mL, 10 mL and 30 mL vials and 7.5 mg(base)/mL, 10 mL and 30 mL vials); New Drug Application (NDA) 20997, held by Purdue Pharma LP, has been voluntarily withdrawn from sale for reasons of safety or efficacy.

B. Statement of Grounds

CHIROCAINE® (Levobupivacaine Injection 2.5 mg(base)/mL, 10 mL and 30 mL vials, 5 mg(base)/mL, 10 mL and 30 mL vials and 7.5 mg(base)/mL, 10 mL and 30 mL vials); New Drug Application (NDA) 20997, held by Purdue Pharma LP, was approved on August 5, 1999 and was designated as the Reference Listed Drug from the time of approval until May of 2004 when the NDA was moved to the discontinued section of the Orange Book. The NDA sponsor, Purdue Pharma LP formally requested withdrawal of CHIROCAINE® Injection and FDA subsequently published a Federal Register Notice on March 7, 2005 acknowledging withdrawal of CHIROCAINE® Injection NDA 20997. CHIROCAINE® Injection remains listed with a Marketing Status of Discontinued in the Orange Book. Please see following notation obtained on December 16, 2022 from the electronic orange book

Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
DISCN	LEVOBUPIVACAINE HYDROCHLORIDE	CHIROCAINE	N020997	INJECTABLE	INJECTION	EQ 2.5MG BASE/ML				PURDUE PHARMA LP
DISCN	LEVOBUPIVACAINE HYDROCHLORIDE	CHIROCAINE	N020997	INJECTABLE	INJECTION	EQ 5MG BASE/ML				PURDUE PHARMA LP
DISCN	LEVOBUPIVACAINE HYDROCHLORIDE	CHIROCAINE	N020997	INJECTABLE	INJECTION	EQ 7.5MG BASE/ML				PURDUE PHARMA LP

If an RLD appears in the discontinued section of the Orange Book and the FDA has not determined whether the drug was withdrawn from sale for reasons of safety or efficacy, a person wishing to submit an ANDA for the drug must submit a citizen petition under 21 C.F.R. § 10.25(a) and § 10.30 before, or at the same time of the ANDA submission, seeking a determination on whether the listed drug has been withdrawn from sale for safety or efficacy reasons. Such a petition must contain all evidence available to the petitioner concerning the reason that the drug product was withdrawn from sale under 21 C.F.R. § 314.122(a).

The regulations provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or efficacy before an ANDA that refers to that listed drug may be approved (21 C.F.R. § 314.161 (a)(1)).

If the FDA determines that the listed drug was withdrawn from sale for reasons of safety and efficacy (or if FDA withdraws or suspends NDA approval for reasons of safety or efficacy), then the drug listing is removed from the Orange Book. See id. *See* 21 C.F.R. § 314.122, § 314.161, and § 314.162. If FDA determines that the listed drug was not withdrawn from sale for reasons of safety and efficacy, then the drug listing remains in the Orange Book and may be cited in an ANDA as an RLD.

Petitioner is further unaware of any reason why CHIROCAINE® Injection, may have been removed from sale and believes the discontinuation of CHIROCAINE® Injection was due to commercial considerations. Petitioner requests that FDA determine whether the NDA holder for CHIROCAINE® INJECTION has withdrawn their products for reason of safety or efficacy.

C. Environmental Impact

In Accordance with the requirements set forth in 21 C.F.R. § 25.31(a), the petitioner hereby requests a Categorical Exclusion from the requirements to prepare an Environmental Impact Assessment. An assessment is not required because the requested action would not increase the use of the active moiety that is the subject of this petition.

D. 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. The Petitioner hereby commits to promptly provide this information, if so requested.

E. Certification

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

Sincerely,

Martin Shimer Digitally signed by Martin Shimer
Date: 2022.12.21 08:12:36 -05'00'

Martin H. Shimer
Executive Director
Lachman Consultant Services, Inc.