March 29, 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of the Food and Drug Administration to provide a determination on whether a listed drug has been voluntarily withdrawn for reasons of safety or efficacy as outlined below.

A. Action Requested

The Petitioner requests that the Commissioner of the Food and Drug Administration determine whether the Reference Listed Drug (RLD), CLEOCIN PHOSPHATE IN DEXTROSE 5% IN PLASTIC CONTAINER® (clindamycin injection in 5% dextrose), EQ 6MG BASE/ML, EQ 12MG BASE/ML, EQ 18MG BASE/ML, New Drug Application (NDA) Number N050639, held by PFIZER INC., has been voluntarily withdrawn from the commercial market or withdrawn from sale for reasons of safety or efficacy.

B. Statement of Grounds

CLEOCIN PHOSPHATE IN DEXTROSE 5% IN PLASTIC CONTAINER® (clindamycin injection in 5% dextrose), EQ 6MG BASE/ML and EQ 12MG BASE/ML, were approved under N050639, held by PFIZER INC., on August 30, 1989, while the EQ 18MG BASE/ML was approved on April 10, 1991, also under NDA N050639. All three strengths are currently listed as the Reference Listed Drug with a Marketing Status of Discontinued. Please see notation below obtained on 3/15/2022 from the electronic orange book at:
https://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm

Search Results for Proprietary Name, Active Ingredient or Application Number: *050639*

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Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
DISCN	CLINDAMYCIN PHOSPHATE	CLEOCIN PHOSPHATE IN DEXTROSE 5% IN PLASTIC CONTAINER	N050639	INJECTABLE	INJECTION	EQ 6MG BASE/ML		RLD		PFIZER INC
DISCN	CLINDAMYCIN PHOSPHATE	CLEOCIN PHOSPHATE IN DEXTROSE 5% IN PLASTIC CONTAINER	N050639	INJECTABLE	INJECTION	EQ 12MG BASE/ML		RLD		PFIZER INC
DISCN	CLINDAMYCIN PHOSPHATE	CLEOCIN PHOSPHATE IN DEXTROSE 5% IN PLASTIC CONTAINER	N050639	INJECTABLE	INJECTION	EQ 18MG BASE/ML		RLD		PFIZER INC

Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	>RLD	RS	Applicant Holder

Showing 1 to 3 of 3 entries

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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 or 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 or 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 CLEOCIN PHOSPHATE IN DEXTROSE 5% IN PLASTIC CONTIANER® may have been removed from sale and believes the discontinuation of CLEOCIN PHOSPHATE IN DEXTROSE 5% IN PLASTIC CONTIANER® , EQ 6MG BASE/ML, EQ 12MG BASE/ML and EQ 18MG BASE/ML was due to commercial considerations. Petitioner requests that FDA determine whether the NDA holder for CLEOCIN PHOSPHATE IN DEXTROSE 5% IN PLASTIC CONTIANER® (clindamycin injection in 5% dextrose), EQ 6MG BASE/ML, EQ 12MG BASE/ML and EQ 18MG BASE/ML, N050639, held by PFIZER has withdrawn the product for reasons 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.

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 is unfavorable to the petition, at the time of submission of the petition.

Sincerely,

Michelle R. Ryder

Digitally signed by Michelle R. Ryder
Date: 2022.03.29 09:52:11 -06'00'

Michelle R. Ryder
Executive Director
Lachman Consultant Services, Inc.