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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 or Madam:

The undersigned hereby submits this Citizen Petition pursuant to 21 CFR 10.30, and in accordance with the regulations at 21 CFR 314.161, requesting the Commissioner of Food and Drugs to provide a determination whether a listed drug has been voluntarily withdrawn for safety or effectiveness reasons as outlined below.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 CLAFORAN® (Cefotaxime Sodium for Injection, 500 mg, 1g, 2g, and 10g/vial, NDA 050547) held by US Pharmaceutical Holdings II LLC have been voluntarily withdrawn from the commercial market or withdrawn from sale for safety or efficacy reasons.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products in the Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"). These drug products are eligible for submission under Section 505(j) of the Federal Food, Drug and Cosmetic Act ("FD&C Act") as Abbreviated New Drug Applications ("ANDAs") or for reference as part of a 505(b)(2) New Drug Application ("NDA"). CLAFORAN® (Cefotaxime Sodium for Injection, 500 mg, 1g, 2g, and 10g/vial, NDA 050547) held by US Pharmaceutical Holdings II LLC was approved by FDA prior to January 1, 1982 per the Orange Book. All strengths appear in the Orange Book as discontinued presented below

Marketing Status	Active Ingredient	Proprietary Name	Appl Number	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
DISCN	CEFOTAXIME SODIUM	CLAFORAN	N050547	INJECTABLÉ	INJECTION	EQ 500MG BASE/VIAL		RLD		US PHARMACEUTICAL HOLDINGS II LLC

DISCN	CEFOTAXIME SODIUM	CLAFORAN	N050547	INJECTABLE	INJECTION	EQ 1GM BASE/VIAL		RLD	US PHARMACEUTICAL HOLDINGS II LLC
DISCN	CEFOTAXIME SODIUM	CLAFORAN	N050547	INJECTABLE	INJECTION	EQ 2GM BASE/VIAL		RLD	US PHARMACEUTICAL HOLDINGS II LLC
DISCN	CEFOTAXIME SODIUM	CLAFORAN	N050547	INJECTABLE	INJECTION	EQ 10GM BASE/VIAL		RLD	US PHARMACEUTICAL HOLDINGS II LLC

If a listed drug has ceased to be offered for sale by its manufacturer, a person wishing to submit an ANDA or a 505(b)(2) NDA referencing the listed drug must petition FDA for a determination of whether the drug was withdrawn for reasons of safety or effectiveness (see 21 CFR 314.161). If FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness, then the drug listing is removed from The Orange Book (see 21 CFR 314.122, 314.161, and 314.162).

The electronic Orange Book, accessed on January 30, 2019, indicates that US Pharmaceutical Holdings II LLC is not marketing CLAFORAN (Cefotaxime for Injection), in the following strengths:500 mg, 1g, 2g, and 10g. Therefore, because all strengths have been discontinued from marketing, the Petitioner hereby requests that the FDA determine whether the applicant's decision to discontinue marketing of the aforementioned product was for reasons of safety or effectiveness.

C. Environmental Impact

The Petitioner claims a categorical exclusion under 21 CFR 25.31.

D. Economic Impact Statement

The Petitioner will, upon request by the Commissioner, submit economic impact information in accordance with 21 CFR 10.30(b).

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 Petition relies, and that it includes representative data and information known to the Petitioner that are unfavorable to the Petition.

Respectfully Submitted,

Boyd Lund
Cardinal Health Regulatory Sciences