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the Food and Drug Administration to provide a determination on whether a listed drug formulation has been voluntarily withdrawn for reasons of safety or efficacy as outlined below.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 original formulation submitted for the Reference Listed Drug (RLD), ADRENALIN® (Epinephrine Injection USP, 30 mg/ 30 mL) (1 mg/ mL) (Multiple Dose Vials); New Drug Application (NDA) 204640, held by PAR STERILE PRODUCTS LLC, has been voluntarily withdrawn from the commercial market or withdrawn from sale for reasons of safety or efficacy.

B. Statement of Grounds

ADRENALIN® (Epinephrine Injection USP, 30 mg/ 30 mL) (1 mg/ mL) (Multiple Dose Vials); New Drug Application (NDA) 204640, held by PAR STERILE PRODUCTS LLC, was Approved on December 18, 2013, and is currently listed in the Orange Book as the Reference Listed Drug. 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: *adrenalin*

RX OTC DISCN

CSV Excel Print

Display 50 records per page

Showing 1 to 2 of 2 entries

Search for text in the table

Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
RX	EPINEPHRINE	ADRENALIN	N204200	SOLUTION	INTRAMUSCULAR, INTRAVENOUS, SUBCUTANEOUS	EQ 1MG BASE/ML (EQ 1MG BASE/ML)		RLD	RS	PAR STERILE PRODUCTS LLC
RX	EPINEPHRINE	ADRENALIN	N204640	SOLUTION	INTRAMUSCULAR, INTRAVENOUS, SUBCUTANEOUS	EQ 30MG BASE/30ML (EQ 1MG BASE/ML)	AP	RLD	RS	PAR STERILE PRODUCTS LLC
Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	>RLD	RS	Applicant Holder

Showing 1 to 2 of 2 entries

Previous 1 Next

Per Drugs@fda.gov, the Package Insert approved on 12/18/2013 with the original NDA 204640 application contained the following statement regarding formulation:

> "In the 30 mL vial, each 1 mL of Adrenalin® solution contains 1 mg epinephrine, 9.0 mg sodium chloride, 1.5 mg sodium metabisulfite, hydrochloric acid to adjust pH, 5.4 mg chlorobutanol as a preservative and water for injection. The pH range is 2.2-5.0."

The current Package Insert approved on 1/29/2019 via Supplement 9 to NDA 204640 contains the following statement regarding formulation:

> "In the 30 mL vial, each 1 mL of Adrenalin solution contains 1 mg epinephrine, 6.15 mg sodium chloride, 0.457 mg sodium metabisulfite, 0.920 mg sodium hydroxide, 2.25 mg tartaric acid, 0.20 mg disodium edetate dihydrate, hydrochloric acid to adjust pH, 5.25 mg chlorobutanol as a preservative and water for injection. The pH range is 2.2-5.0"

Although the RLD does not appear in the discontinued section of the Orange Book, a sponsor wishing to submit an ANDA referencing the *original* formulation (approved on 12/18/2013) of the RLD 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 original formulation of the 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 formulation is withdrawn from sale for reasons of safety or efficacy before an ANDA that refers to that listed drug formulation may be approved (21 C.F.R. § 314.161 (a)(1)).

Petitioner is further unaware of any reason why the original formulation for ADRENALIN® (Epinephrine Injection USP, 30 mg/ 30 mL) (1 mg/ mL) (Multiple Dose Vials) may have been removed from sale and believes the change in formulation was due to considerations other than safety or efficacy. Petitioner requests that FDA determine whether the original formulation for ADRENALIN® (Epinephrine Injection USP, 30 mg/ 30 mL) (1 mg/ mL) (Multiple Dose Vials); New Drug Application (NDA) 204640, held by PAR STERILE PRODUCTS LLC was withdrawn 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.

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 09:34:46 -06'00'

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