

May 01, 2019

Division of Dockets Management
Food and Drug Administration (HF A-305)
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir or Madam:

The undersigned submits this petition on behalf of a client, pursuant to Federal Food, Drug, and Cosmetic Act (“FD&C 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Commissioner of Food and Drug Administration to provide a determination on whether a listed drug has been voluntarily withdrawn for safety or effectiveness reasons as outlined below.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 Reference Listed Drug (RLD), ATROPINE SULFATE ANSYR PLASTIC SYRINGE® [Atropine Sulfate Solution; Intravenous, Intramuscular, Subcutaneous, Endotracheal; 0.5mg/5mL (0.1 mg/mL)], New Drug Application (NDA) Number 021146, held by HOSPIRA INC, has been voluntarily withdrawn from the commercial market or withdrawn from sale for safety or effectiveness reasons.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products in the Orange Book. The list, Approved Drug Products with Therapeutic Equivalence Evaluations, referred to as the “Orange Book”, lists all FDA approved drug products. These drug products are eligible for submission under Section 505(j) of the FD&C Act as ANDAs. ATROPINE SULFATE ANSYR PLASTIC SYRINGE® [Atropine Sulfate Solution; Intravenous, Intramuscular, Subcutaneous, Endotracheal; 0.5mg/5mL (0.1 mg/mL)], New Drug Application (NDA) Number 021146, held by HOSPIRA INC., was approved on July 09, 2001. The product was then considered to be a “listed drug product” in the Orange Book. ATROPINE SULFATE ANSYR PLASTIC SYRINGE® [Atropine Sulfate Solution; Intravenous, Intramuscular, Subcutaneous, Endotracheal; 0.5mg/5mL (0.1 mg/mL)] now appears in the “Discontinued Section” of the Orange Book (refer Attachment A), indicating that they are currently not available for sale.

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determined whether the drug was withdrawn from sale for reasons of safety or effectiveness, the applicant must submit a citizen petition under 21 C.F.R. § 10.25(a) and § 10.30 before or at the same time as the ANDA submission, seeking a determination on whether the listed drug has been withdrawn from sale for safety or effectiveness reasons.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). If the 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 C.F.R. § 314.122, § 314.161, and § 314.162.

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 effectiveness before an ANDA that refers to that listed drug may be approved (21 C.F.R. § 314.161 (a)(1)).

Petitioner is further unaware of any reason why ATROPINE SULFATE ANSYR PLASTIC SYRINGE® [Atropine Sulfate Solution; Intravenous, Intramuscular, Subcutaneous, Endotracheal; 0.5mg/5mL (0.1 mg/mL)] may have been removed from sale and believes the discontinuation of ATROPINE SULFATE ANSYR PLASTIC SYRINGE® [Atropine Sulfate Solution; Intravenous, Intramuscular, Subcutaneous, Endotracheal; 0.5mg/5mL (0.1 mg/mL)] was due to only commercial considerations. Petitioner requests that FDA determine whether the NDA holder for ATROPINE SULFATE ANSYR PLASTIC SYRINGE® [Atropine Sulfate Solution; Intravenous, Intramuscular, Subcutaneous, Endotracheal; 0.5mg/5mL (0.1 mg/mL)] (NDA Number 021146) has withdrawn the product for reason of safety or effectiveness.

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 Statement

The petitioner will, upon request by the Commissioner, submit economic impact information, in accordance with 21 C.F.R. § 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, which are unfavorable to the petition.

Sincerely,

Sharif Ahmed
Principal Consultant

Attachment A
Current (May 1, 2019) Orange Book Listing of Atropine Sulfate Solution; NDA 021146 held by HOSPIRA INC.

Mkt. Status	Active Ingredient	Proprietary Name	Appl. No	Dosage Form	Route	Strength	RLD	RS	Applicant Holder	Approval Date
RX	ATROPINE SULFATE	ATROPINE SULFATE ANSYR PLASTIC SYRINGE	N021146	SOLUTION	INTRAVENOUS, INTRAMUSCULAR, SUBCUTANEOUS, ENDOTRACHEAL	0.25MG/5ML (0.05MG/ML)	RLD	RS	HOSPIRA INC	Jul 9, 2001
RX	ATROPINE SULFATE	ATROPINE SULFATE ANSYR PLASTIC SYRINGE	N021146	SOLUTION	INTRAVENOUS, INTRAMUSCULAR, SUBCUTANEOUS, ENDOTRACHEAL	1MG/10ML (0.1MG/ML)	RLD	RS	HOSPIRA INC	Jul 9, 2001
DISCN	ATROPINE SULFATE	ATROPINE SULFATE ANSYR PLASTIC SYRINGE	N021146	SOLUTION	INTRAVENOUS, INTRAMUSCULAR, SUBCUTANEOUS, ENDOTRACHEAL	0.5MG/5ML (0.1MG/ML)	RLD		HOSPIRA INC	Jul 9, 2001
RX	ATROPINE SULFATE	ATROPINE SULFATE LIFESHIELD ABBOJECT SYRINGE	N021146	SOLUTION	INTRAVENOUS	0.5MG/5ML (0.1MG/ML)	RLD	RS	HOSPIRA INC	Aug 17, 2017
RX	ATROPINE SULFATE	ATROPINE SULFATE LIFESHIELD ABBOJECT SYRINGE	N021146	SOLUTION	INTRAVENOUS	1MG/10ML (0.1MG/ML)	RLD	RS	HOSPIRA INC	Aug 17, 2017