

Rockville, MD 20852 between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500. Publicly available submissions may be seen in the docket.

**FOR FURTHER INFORMATION CONTACT:**

Jaime Espinosa, Division of Compliance and Enforcement, Office of Policy, Compliance, and Enforcement, Office of Regulatory Affairs, Food and Drug Administration, at 240-402-8743, or [debarments@fda.hhs.gov](mailto:debarments@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Section 306(b)(1)(D) of the FD&C Act permits debarment of an individual from importing or offering for import any drug into the United States if FDA finds, as required by section 306(b)(3)(C) of the FD&C Act, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any drug or controlled substance.

On March 2, 2023, Mr. Leonowens was convicted, as defined in section 306(l)(1) of FD&C Act, in the U.S. District Court for the Western District of Michigan, when the court entered judgment against him for the offense of conspiracy to smuggle goods into the United States in violation of 18 U.S.C. 371 and 545. FDA's finding that debarment is appropriate is based on the felony conviction referenced herein.

The factual basis for this conviction is as follows: As contained in the Information and Plea Agreement from Mr. Leonowens' case, filed on April 27, 2022, and April 28, 2022, respectively, Brendon Gagne owned and operated [www.ExpressPCT.com](http://www.ExpressPCT.com), which sold misbranded prescription drugs, obtained from overseas suppliers, to customers in the United States without requiring a prescription. In exchange for obtaining Modafinil for himself, Mr. Leonowens conspired with Brendon Gagne and agreed to receive, repackage, and reship prescription drugs that Mr. Leonowens would receive from co-conspirators outside of the United States that were purchased by customers on the website [www.ExpressPCT.com](http://www.ExpressPCT.com). Mr. Leonowens received approximately four packages containing bulk quantities of prescription drugs which were all shipped from overseas, including from Germany, India, and Singapore. Each time Mr. Leonowens received a package, he removed some Modafinil for himself and then sent the rest of the drugs to others. In his plea agreement, Mr. Leonowens acknowledged that he knew that receiving and reshipping prescription drugs in this manner was illegal. Mr. Leonowens also recruited others to join in the scheme by also

receiving and reshipping misbranded prescription drugs from overseas suppliers. In exchange for his participation in the scheme, Mr. Leonowens received free or discounted prescription drugs.

As a result of this conviction, FDA sent Mr. Leonowens, by United Parcel Service, on November 30, 2023, a notice proposing to debar him for a 5-year period from importing or offering for import any drug into the United States. The proposal was based on a finding under section 306(b)(3)(C) of the FD&C Act that Mr. Leonowens' felony conviction under Federal law for conspiracy to smuggle goods into the United States in violation of 18 U.S.C. 371 and 545, was for conduct relating to the importation into the United States of any drug or controlled substance because he was involved in a scheme to illegally import and introduce misbranded prescription drugs into the United States. In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C Act that it considered applicable to Mr. Leonowens' offense and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Leonowens of the proposed debarment and offered him an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Leonowens received the proposal and notice of opportunity for a hearing at his residence on December 1, 2023. Mr. Leonowens failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

**II. Findings and Order**

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(3)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Leonowens has been convicted of a felony under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that the offense should be accorded a debarment period of 5 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Mr. Leonowens is debarred for a period

of 5 years from importing or offering for import any drug into the United States, effective (see **DATES**). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of any drug by, with the assistance of, or at the direction of Mr. Leonowens is a prohibited act.

Dated: March 20, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2024-06287 Filed 3-25-24; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2023-N-2853]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Reporting and Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing that a collection of information entitled "Reporting and Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA).

**FOR FURTHER INFORMATION CONTACT:** Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St, North Bethesda, MD 20852, 301-796-8867, [PRASaff@fda.hhs.gov](mailto:PRASaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** On January 26, 2024, the Agency submitted a proposed collection of information entitled "Reporting and Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle" to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

OMB has now approved the information collection and has assigned OMB control number 0910–0623. The approval expires on February 28, 2027. A copy of the supporting statement for this information collection is available on the internet at <https://www.reginfo.gov/public/do/PRAMain>.

Dated: March 21, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2024–06395 Filed 3–25–24; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2023–P–4636]

#### **Determination That ISUPREL (Isoproterenol Hydrochloride) Injection, 0.2 Milligrams per Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) has determined that ISUPREL (isoproterenol hydrochloride) injection, 0.2 milligrams (mg)/milliliter (mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for ISUPREL (isoproterenol hydrochloride) injection, 0.2 mg/mL, if all other legal and regulatory requirements are met.

**FOR FURTHER INFORMATION CONTACT:** Veniqua Stewart, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6219, Silver Spring, MD 20993–0002, 301–796–3627, [Veniqua.Stewart@fda.hhs.gov](mailto:Veniqua.Stewart@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not

have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the “Approved Drug Products With Therapeutic Equivalence Evaluations,” which is known generally as the “Orange Book.” Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

ISUPREL (isoproterenol hydrochloride) injection, 0.2 mg/mL, is the subject of NDA 010515, held by Bausch Health US, LLC, and was initially approved on May 25, 1956. ISUPREL injection is indicated to improve hemodynamic status in patients in distributive shock and shock due to reduced cardiac output, and is also indicated for bronchospasm occurring during anesthesia. ISUPREL (isoproterenol hydrochloride) injection, 0.2 mg/mL, is currently listed in the “Discontinued Drug Product List” section of the Orange Book.

E. Rust Consulting, LLC submitted a citizen petition dated October 20, 2023 (Docket No. FDA–2023–P–4636), under 21 CFR 10.30, requesting that the Agency determine whether ISUPREL (isoproterenol hydrochloride) injection, 0.2 mg/mL, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that ISUPREL (isoproterenol hydrochloride) injection, 0.2 mg/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that ISUPREL (isoproterenol hydrochloride) injection, 0.2 mg/mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ISUPREL

(isoproterenol hydrochloride) injection, 0.2 mg/mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list ISUPREL (isoproterenol hydrochloride) injection, 0.2 mg/mL, in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to ISUPREL (isoproterenol hydrochloride) injection, 0.2 mg/mL, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: March 20, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2024–06311 Filed 3–25–24; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2024–N–0846]

#### **Agency Information Collection Activities; Proposed Collection; Comment Request; National Agriculture and Food Defense Strategy Survey**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements for a voluntary