

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2022-N-1129]

Jennings Ryan Staley: Final Debarment Order**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Jennings Ryan Staley for a period of 5 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. Staley was convicted of one felony count under Federal law for Importation Contrary to Law. The factual basis supporting Mr. Staley's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Staley was given notice of the proposed debarment and was given an opportunity to request a hearing to show why he should not be debarred. Mr. Staley provided notice to FDA that he acquiesced to the debarment; FDA received that notice on October 6, 2022. As such, his debarment commenced on the date FDA was notified of acquiescence.

DATES: This order is applicable October 6, 2022.

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, or at www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement (ELEM-4144), Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240-402-8743, or at debarments@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

Section 306(b)(1)(D) of the FD&C Act (21 U.S.C. 335a(b)(1)(D)) 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 May 27, 2022, Mr. Staley was convicted, as defined in section 306(l)(1) of FD&C Act, in the U.S. District Court for the Southern District of California, when the court accepted his plea of guilty and entered judgment against him for the offense Importation Contrary to Law, in violation of 18 U.S.C. 545 and 2. 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 Plea Agreement in Mr. Staley's case, filed July 16, 2021, as a licensed medical doctor and the proprietor of Skinny Beach Med Spa, Mr. Staley sold "treatment packs" for COVID-19 to members of the public in March and April 2020 in Southern California. Mr. Staley marketed these treatment packs by making statements about the efficacy of the drugs the packs included. For example, Mr. Staley told an undercover agent from the Federal Bureau of Investigation, who posed as a prospective patient, that hydroxychloroquine and mefloquine would cure COVID-19 "one hundred percent" and would provide at least 6 weeks of immunity. Mr. Staley also stated that hydroxychloroquine was a "magic bullet," an "amazing weapon," "almost too good to be true," an "amazing cure," and a "miracle cure" for COVID-19.

To obtain hydroxychloroquine for use in his COVID-19 treatment packs, Mr. Staley contacted merchants in China who could purportedly supply bulk quantities of the drug, including one merchant who could supposedly import kilogram quantities of hydroxychloroquine powder. In Mr. Staley's correspondence with this merchant, he agreed that the merchant would deliberately mislabel the shipment of hydroxychloroquine powder as "yam extract" to fool U.S. Customs and Border Protection (CBP) agents and ensure that the shipment would not be rejected or delayed. In Mr. Staley's plea agreement, he admitted that by mislabeling what he believed to be 12 kilograms of hydroxychloroquine powder as yam extract in violation of 18 U.S.C. 541, he knowingly and willfully intended to deceive CBP and cause the importation of merchandise into the United States upon a false classification of its quality or value. It is immaterial under 18 U.S.C. 541 that the shipment ultimately contained baking soda rather than hydroxychloroquine.

As a result of this conviction, FDA sent Mr. Staley, by certified mail, on September 8, 2022, 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. Staley's felony conviction under Federal law for Importation Contrary to Law, in violation of 18 U.S.C. 545 and 2, was for conduct relating to the importation into the United States of a drug or controlled substance because, in order to defraud CBP, he knowingly and willfully intended to cause the mislabeling and importation of 12 kilograms of what Mr. Staley believed to be hydroxychloroquine powder upon a false classification of its quality or value in violation of 18 U.S.C. 541.

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. Staley's offense and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Staley 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. Staley received the proposal and notice of opportunity for a hearing. Through his attorney, Mr. Staley sent a memorandum to FDA, dated September 26, 2022, wherein he stated that he acquiesced to the proposed debarment. FDA received the memorandum on October 6, 2022. In accordance with section 306(c)(2)(B) of the FD&C Act, Mr. Staley's period of debarment shall commence on the date FDA received notice he acquiesced to the debarment, which was October 6, 2022 (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. Jennings Ryan Staley 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. Staley is debarred for a period of 5 years from importing or offering for import any drug into the United States, effective October 6, 2022. 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. Staley is a prohibited act.

Any application by Mr. Staley for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2022-N-1129 and sent to the Dockets Management Staff (see **ADDRESSES**). The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions will be placed in the docket and will be viewable at <https://www.regulations.gov> or at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

Dated: November 22, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2022-0350; OMB Control Number 1625-0041]

Information Collection Request to Office of Management and Budget

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625-0041, Various International Agreement Pollution Prevention Certificates and Documents, and Equivalency Certificates; without change.

Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before January 30, 2023.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG-2022-0350] to the Coast Guard using the Federal eRulemaking Portal at <https://www.regulations.gov>. See the “Public participation and

request for comments” portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

A copy of the ICR is available through the docket on the internet at <https://www.regulations.gov>. Additionally, copies are available from: Commandant (CG-6P), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr. Ave. SE, Stop 7710, Washington, DC 20593-7710.

FOR FURTHER INFORMATION CONTACT: A.L. Craig, Office of Privacy Management, telephone 202-475-3528, or fax 202-372-8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. 3501 *et seq.*, chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection’s purpose, the Collection’s likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) the practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology.

In response to your comments, we may revise this ICR or decide not to seek an extension of approval for the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG-2022-0350], and must be received by January 30, 2023.

Submitting Comments

We encourage you to submit comments through the Federal

eRulemaking Portal at <https://www.regulations.gov>. If your material cannot be submitted using <https://www.regulations.gov>, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at <https://www.regulations.gov> and can be viewed by following that website’s instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to <https://www.regulations.gov> and will include any personal information you have provided. For more about privacy and submissions in response to this document, see DHS’s eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

Information Collection Request

Title: Various International Agreement Pollution Prevention Certificates and Documents, and Equivalency Certificates.

OMB Control Number: 1625-0041.

Summary: Required by the adoption of the International Convention for the Prevention of Pollution from Ships (MARPOL 73/78) and other international treaties, these certificates and documents are evidence of compliance for U.S. vessels on international voyages. Without the proper certificates or documents, a U.S. vessel could be detained in a foreign port.

Need: Compliance with treaty requirements aids in the prevention of pollution from ships.

Forms:

- CG-5352, International Oil Pollution Prevention Certificate.
- CG-5352A, Form A Supplement to the International Oil Pollution Prevention Certificate (IOPP Certificate).
- CG-5352B, Form B Supplement to the International Oil Pollution Prevention Certificate (IOPP Certificate).
- CG-6047, International Sewage Pollution Prevention Equivalency Certificate.
- CG-6047A, Statement of Voluntary Compliance for Sewage Pollution Prevention.
- CG-6056, International Air Pollution Prevention Certificate.
- CG-6056A, Supplement to International Air Pollution Prevention Certificate.
- CG-6056B, Statement of Voluntary Compliance for Annex VI of MARPOL 73/78.