Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID–19) Public Health Emergency; Guidance for Industry and Food and Drug Administration Staff'' (Ref. 8).

V. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. *Centers for Disease Control. ''Perspectives in Disease Prevention and Health Promotion Update: Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Bloodborne Pathogens in Health-Care Settings.'' *Morbidity and Mortality Weekly Report* 1988; 37(25):377–388.
2. World Health Organization. Glove Use Information Leaflet. 2009. *https://www.who.int/gpsc/5may/Glove_Use_Information_Leaflet.pdf.*
3. *Collins, A.S. ''Preventing Health Care-Associated Infections.'' In: Hughes, R.G., editor. *Patient Safety and Quality: An Evidence-Based Handbook for Nurses.* Rockville (MD): Agency for Healthcare Research and Quality (US); 2008 April. Chapter 41. *https://www.ncbi.nlm.nih.gov/books/NBK2683/pdf/Bookshelf_NBK2683.pdf.*
4. Alexander, J. Wesley, Joseph S. Solomkin, and Michael J. Edwards (2011). ''Updated Recommendations for Control of Surgical Site Infections,'' *Annals of Surgery,* 253(6):1082–1093.
5. Sugarbaker, P.H. (2018). ''Increased Safety of Surgical Glove Application: The Under/Over Method'' *Annals of the Royal College of Surgeons of England,* 100(4):339–340.
6. Landeck, L., E. Gonzalez, and O.M. Koch. ''Handling Chemotherapy Drugs—Do Medical Gloves Really Protect?'' *International Journal of Cancer.* 2015 October 15;137(8):1800–5. doi: 10.1002/ijc.29058. Epub 2014 July 22. PMID: 24978061
7. Nalin, M., G. Hug, E. Boeckmans, C. Machon, et al. ''Permeation Measurement of 27 Chemotherapy Drugs After Simulated Dynamic Testing on 15 Surgical And Examination Gloves: A Knowledge Update.'' *Journal of Oncology Pharmacy Practice.* 2020 Aug 26:1078155220950423. doi: 10.1177/1078155220950423. Epub ahead of print. PMID: 32847481.
8. *FDA Guidance, ''Enforcement Policy for Gown, Other Apparel, and Gloves During the Coronavirus Disease (COVID–19) Public Health Emergency, Guidance for Industry and Food and Drug Administration Staff,'' March 25, 2020, available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-gowns-other-apparel-and-gloves-during-coronavirus-disease-covid-19-public-health.*

Dated: July 12, 2021.

Janet Woodcock,

Acting Commissioner of Food and Drugs.

Dated: July 21, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–15891 Filed 7–23–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2149]

Jonathan Doyle: 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 Jonathan Doyle for a period of 5 years from importing articles of food or offering such articles for importation into the United States. FDA bases this order on a finding that Mr. Doyle was convicted of a felony count under Federal law for conduct relating to the importation into the United States of an article of food. Mr. Doyle was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of April 8, 2021 (30 days after receipt of the notice), Mr. Doyle has not responded. Mr. Doyle's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

DATES: This order is applicable July 26, 2021.

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 *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement (ELEM–4029), 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)(C) of the FD&C Act (21 U.S.C. 335a(b)(1)(C)) permits FDA to debar an individual from importing an article of food or offering such an article for import into the United States if FDA finds, as required by section 306(b)(3)(A) 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 food.

On October 15, 2020, Mr. Doyle was convicted as defined in section 306(*l*)(1)(A) of the FD&C Act, in the U.S. District Court for the Northern District of Texas-Dallas Division, when the court accepted Mr. Doyle's plea of guilty and entered judgment against him for the offense of conspiracy to introduce misbranded food into interstate commerce with an intent to defraud and mislead in violation of 18 U.S.C. 371 (21 U.S.C. 331(a) and 21 U.S.C. 333(a)(2)).

FDA's finding that the debarment is appropriate is based on the felony conviction referenced herein. The factual basis for this conviction is as follows: As contained in the factual résumé, dated February 15, 2019, in Mr. Doyle's case, he was the President of USPlabs, LLC (USP Labs), and owned 45 percent of the company. USP Labs sold dietary supplements. Beginning in or around October 2008 and continuing until at least in or around August 2014, Mr. Doyle engaged in a conspiracy with others to import and ship in interstate commerce a variety of chemicals for use and prospective use in dietary supplements with false labeling. To further this conspiracy, Mr. Doyle's coconspirators ordered chemicals from Chinese chemical sellers to be used as ingredients in dietary supplements and had them labeled falsely as other food substances. USP Labs sold dietary supplements called Jack3d and OxyElite Pro, both of which originally contained a substance called 1,3-dimethylamylamine (DMAA), which is also known as methylhexaneamine. USP Labs imported numerous substances intended for human consumption, including DMAA, using false and fraudulent Certificates of Analysis (COA) and other false and fraudulent documentation and labeling. At least some of the false COAs that USP Labs

caused to be created for their DMAA shipments stated falsely that the substance in the shipments had been extracted from the geranium plant. Further, on or about December 8, 2011, Mr. Doyle's coconspirator instructed a Chinese chemical seller via email to misbrand a shipment of nine different chemicals sent from China to USP Labs in Texas. One of those synthetic chemicals was called ''aegeline.'' The first aegeline-containing version of OxyElite Pro, which was called OxyElite ''New Formula,'' went on sale in December 2012. In summer 2013, USP Labs reformulated the product again to contain aegeline and powder derived from a Chinese herb called cynanchum auriculatum. On or about June 15, 2013, Mr. Doyle's coconspirator instructed a Chinese chemical seller to have two metric tons of ground cynanchum auriculatum root powder shipped internationally to SK Laboratories in California for inclusion in USP Labs' products, using the false name ''cynanchum auriculatum root extract.'' USP Labs sent false labels listing ''cynanchum auriculatum (root) extract'' as an ingredient in its OxyElite Pro ''Advanced Formula'' supplement, even though that ingredient was not present in the product. The conspirators collected millions in revenue that they would not have obtained, absent the conspiracy.

As a result of this conviction FDA sent Mr. Doyle, by certified mail on March 4, 2021, a notice proposing to debar him for a period of 5 years from importing articles of food or offering such articles for import into the United States. The proposal was based on a finding under section 306(b)(1)(C) of the FD&C Act that Mr. Doyle's felony conviction of conspiracy to introduce misbranded food into interstate commerce with an intent to defraud and mislead in violation of 18 U.S.C. 371 (21 U.S.C. 331(a) and 21 U.S.C. 333(a)(2)), constitutes conduct relating to the importation into the United States of an article of food because the offense involved a conspiracy to import a variety of chemicals with false labeling in order to either use those chemicals in dietary supplements which would themselves also contain false labeling or to determine whether those chemicals could be used in new dietary supplements.

The proposal was also based on a determination, after consideration of the relevant factors set forth in section 306(c)(3) of the FD&C Act, that Mr. Doyle should be subject to a 5-year period of debarment. The proposal also offered Mr. Doyle an opportunity to request a hearing, providing Mr. Doyle 30 days from the date of receipt of the letter in which to file the request, and advised Mr. Doyle that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Doyle failed to respond 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)(1)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Jonathan Doyle has been convicted of a felony count under Federal law for conduct relating to the importation into the United States of an article of food and that he is subject to a 5-year period of debarment.

As a result of the foregoing finding, Mr. Doyle is debarred for a period of 5 years from importing articles of food or offering such articles for import into the United States, effective July 26, 2021. 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 an article of food by, with the assistance of, or at the direction of Jonathan Doyle is a prohibited act.

Any application by Mr. Doyle for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2020–N–2149 and sent to the Dockets Management Staff (**ADDRESSES**). The public availability of information in these submissions is governed by 21 CFR 10.20.

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: July 19, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–15775 Filed 7–23–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: COVID–19 Provider Relief Fund Reporting Activities, OMB No. 0906–XXXX New

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than September 24, 2021.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: COVID–19 Provider Relief Fund Reporting Activities, OMB No. 0906–XXXX New.

Abstract: HRSA administers the Provider Relief Fund (PRF), which has disbursed funds to eligible health care providers to support health care-related expenses or lost revenues attributable to the COVID–19 pandemic. Providers who have accepted the Terms and Conditions regarding their PRF payment(s), including the requirement that the provider ''shall submit reports as the Secretary determines are needed to ensure compliance with conditions that are imposed on this Payment, and