

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.*

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## 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](mailto: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](mailto: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

such reports shall be in such form, with such content, as specified by the Secretary in future program instructions directed to all Recipients," will be using the PRF Reporting Portal to submit information about their use of PRF payments. HRSA is currently operating under the Paperwork Reduction Act Public Health Emergency (PHE) waiver that was approved by the Office of the Assistant Secretary for Planning and Evaluation on January 14, 2021. In anticipation of the PHE waiver expiring, HRSA is undergoing the OMB clearance process as the data will be collected beyond the PHE.

*Need and Proposed Use of the Information:* Recipients of a PRF payment agreed to a set of Terms and Conditions, which, among other requirements, mandate compliance with certain reporting requirements that will facilitate appropriate oversight of recipients' use of funds.

Information collected will allow for (1) assessing whether recipients have met statutory and programmatic requirements, (2) conducting audits, (3) gathering data required to report on findings with respect to the disbursements of PRF payments, and (4) program evaluation. HRSA staff will

also use information collected to identify and report on trends in health care metrics and expenditures before and during the allowable period for expending PRF payments.

*Likely Respondents:* PRF recipients who have received more than \$10,000 in aggregate PRF payments during one of the Payment Received Periods outlined below and that agreed to the associated Terms and Conditions are required to submit a report in the PRF Reporting Portal during the applicable Reporting Time Period.

Reporting period	Payment received period (payments exceeding \$10,000 in aggregate received)	Reporting time period
Period 1 .....	April 10, 2020, to June 30, 2020 .....	July 1, 2021, to September 30, 2021.
Period 2 .....	July 1, 2020, to December 31, 2020 .....	January 1, 2022, to March 31, 2022.
Period 3 .....	January 1, 2021, to June 30, 2021 .....	July 1, 2022, to September 30, 2022.
Period 4 .....	July 1, 2021, to December 31, 2021 .....	January 1, 2023, to March 31, 2023.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize

technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search

data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

#### TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
PRF Reporting Portal, Reporting Period 1 (Providers who received payments April 10, 2020, to June 30, 2020) .....	126,831	1	126,831	5.6	710,254
PRF Reporting Portal, Reporting Period 2 (Providers who received payments July 1, 2020, to December 31, 2020) .....	120,536	1	120,536	4.2	506,251
PRF Reporting Portal, Reporting Period 3 (Providers who received payments January 1, 2021, to June 30, 2021) .....	19,962	1	19,962	5.6	111,787
PRF Reporting Portal, Reporting Period 4 (Providers who received payments July 1, 2021, to December 31, 2021) .....	19,962	1	19,962	5.6	111,787
Total .....	287,291	.....	287,291	.....	1,440,079

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**Maria G. Button,**

*Director, Executive Secretariat.*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Meeting of the Tick-Borne Disease Working Group

**AGENCY:** Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** As required by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that the Tick-Borne Disease Working

Group (TBDWG) will hold a virtual meeting. The meeting will be open to the public. For this meeting, TBDWG members will focus on plans to develop the next report due December 2022 on federal tick-borne activities and research, taking into consideration the 2018 and 2020 reports. The 2022 report will address a wide range of topics related to tick-borne diseases, such as, surveillance, prevention, diagnosis, diagnostics, and treatment; identify advances made in research, as well as overlap and gaps in tick-borne disease research; and provide recommendations regarding any appropriate changes or