

regarding this collection contact Adam Pellillo at (667) 290-9621.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impact Analysis, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Office of Management and Budget #: 0970-0473]

Submission for Office of Management and Budget Review; Child Care and Development Fund (CCDF) Consumer Education Website and Reports of Serious Injuries and Death

AGENCY: Office of Child Care, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office of Child Care, Administration for Children and Families (ACF), U.S. Department of Health and Human Services, is requesting a 3-year extension of the Child Care and Development Fund (CCDF) Consumer Education website and Reports of Serious Injuries and Death (Office of Management and

Budget)#: 0970-0473, expiration date: May 31, 2026). There are no changes requested to the reporting requirements. Burden estimates have been adjusted.

DATES: *Comments due* June 15, 2026.

ADDRESSES: The public may view and comment on this information collection request at: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202605-0970-003. You can also obtain copies of the proposed collection of information by emailing infocollection@acf.hhs.gov. Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The existing *Consumer Education Website reporting requirement* will not be modified and requires states and territories to include information about state or territory policies (related to licensing, monitoring, and background checks) and provider-specific information, including results of monitoring and inspection reports, and if available, information about quality. The existing *Reporting of Serious Injuries and Death reporting requirement* will not be modified. CCDF lead agencies must establish procedures that require child care providers that care for children receiving CCDF subsidies to report to a designated state, territorial, or tribal entity any serious injuries or deaths of children occurring in child care. There are no standard federal forms associated with these reporting requirements.

Respondents: The *Consumer Education Website* requirement applies to the 50 states, the District of Columbia, and 5 territories that receive CCDF grants. *Reporting of Serious Injuries and Death* is a requirement for child care providers receiving CCDF subsidies within states, territories, and tribes.

Annual Burden Estimates

The *burden estimates for the consumer education website* requirement at § 98.33 have been reduced based on analysis of the federal fiscal year 2025-2027 CCDF State and Territory Plans. Eighteen out of 56 lead agencies are non-compliant on requirements related to their consumer education websites and would incur burden under this renewal, while the remaining grantees have demonstrated compliance and would experience minimal burden for ongoing maintenance to their consumer education websites. Accordingly, the burden hours for those 38 lead agencies only needing ongoing maintenance has been reduced from 300 to 50 average hours, resulting in an overall reduction of approximately 57 percent in total annual burden hours compared to the previously approved version. The *burden estimates for reporting serious injuries and deaths* at § 98.42 remain unchanged, as the burden is limited to provider reporting when a reportable event occurs. States and territories have flexibility in how they structure the provider reporting.

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Consumer Education Website Development and Maintenance	18	1	300	5,400
Consumer Education Website Maintenance	38	1	50	1,900
Reporting of Serious Injuries and Death	10,000	1	1	10,000
Estimated Total Annual Burden Hours				17,300

(Authority: Pub. L. 113-186; 42 U.S.C. 9858 *et seq.*)

Mary C. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-0421]

Oscar Bobo: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debaring Oscar Bobo 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. Bobo engaged in a pattern of importing or offering for import misbranded drugs (*i.e.*, in an amount, frequency, or dosage that is inconsistent with his personal or household use) that are not designated in an authorized electronic data interchange system as products regulated by FDA. Mr. Bobo was given notice of the proposed debarment and was given an opportunity to request a hearing to show why he should not be debarred. As of March 25, 2026 (30 days after receipt of the notice), Mr. Bobo had not responded. Mr. Bobo'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 May 15, 2026.

ADDRESSES: Any application by Mr. Bobo for termination of debarment under section 306(d)(1) of the FD&C Act (21 U.S.C. 335a(d)(1)) may be submitted at any time as follows:

Electronic Submissions

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. An application submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your application, that information will be posted on <https://www.regulations.gov>.

- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All applications must include the Docket No. FDA-2025-N-0421. Received applications will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions—**To submit an application with confidential information that you do not wish to be

made publicly available, submit your application only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of your application. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, 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 Field Enforcement, Office of Field Regulatory Operations, Office of Inspections and Investigations, Food and Drug Administration, at 240-402-8743, or 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)(D) of the FD&C Act, that the individual has engaged in a pattern of importing or offering for import (*i.e.*, in an amount, frequency, or dosage that is inconsistent with personal or household use) misbranded drugs that are not designated in an authorized electronic data interchange system as products regulated by FDA.

After an investigation, FDA discovered that Mr. Bobo had engaged in numerous instances of importing or offering for import misbranded drugs. Specifically, between April 5, 2019, and September 3, 2024, Mr. Bobo imported or offered for import 8 parcels containing a total of 10 products (5,970 tablets) that contained tadalafil and sildenafil. FDA determined that these drugs were misbranded because their labeling lacked adequate directions for use, as required by section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)), and/or because the drugs were prescription drugs and their labels failed to bear the symbol "Rx only" as required by section 503(b)(4)(A) of the FD&C Act (21 U.S.C. 353(b)(4)(A)). All the parcels containing the misbranded drugs serving as the basis for this action were intercepted by FDA at the John F. Kennedy International Mail Facility and were addressed to Mr. Bobo at an address connected to him.

As a result of this pattern of importing or offering for import (*i.e.* in an amount, frequency, or dosage that is inconsistent with personal or household use) misbranded drugs that are not designated in an authorized electronic data interchange system as products regulated by FDA, in accordance with section 306(b)(3)(D) of the FD&C Act, FDA sent Mr. Bobo, by certified mail on February 17, 2026, a notice proposing to debar him for a 5-year period from importing or offering for import any drug into the United States. The attachment to that notice contained a table listing all the parcels intercepted by FDA that contained the misbranded drugs serving as a basis for this action. Among other pieces of information, that table contained the submission date of the entry, the product contained in the package, the quantity of the product, and the product violation FDA found for each entry. That attachment is posted to the docket and can be accessed by the public at <https://www.regulations.gov>.

In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C Act that the Agency considered applicable to Mr. Bobo's pattern of conduct and concluded that his conduct warranted the imposition of a 5-year period of debarment. The proposal informed Mr. Bobo 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. Bobo received the proposal and notice

of opportunity for a hearing on February 23, 2026. Mr. Bobo 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 Division of Field Enforcement Director, Office of Inspections and Investigations, under section 306(b)(3)(D) of the FD&C Act, under authority delegated to the Director, Division of Enforcement, finds that Mr. Oscar Bobo has engaged in a pattern of importing or offering for import (*i.e.*, in an amount, frequency, or dosage that is inconsistent with his personal or household use) misbranded drugs that are not designated in an authorized electronic data interchange system as products regulated by the FDA. FDA finds that this pattern of conduct 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. Bobo 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. Bobo during his period of debarment is a prohibited act.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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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: Data System for Organ Procurement and Transplantation Network, OMB No. 0906-0110—Revision

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

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 July 14, 2026.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 13N82, 5600 Fishers Lane, Rockville, Maryland 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 Samantha Miller, the HRSA Information Collection Clearance Officer, at (301) 443-3983.

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

Information Collection Request Title: Data System for Organ Procurement and Transplantation Network, OMB No. 0906-0110—Revision

Abstract: Section 372 of the Public Health Service Act requires that the Secretary of HHS, by awards, provide for the establishment and operation of the Organ Procurement and Transplantation Network (OPTN), which, under HRSA's oversight, operates the U.S. organ procurement and transplantation system. HRSA, in alignment with the Paperwork Reduction Act of 1995, submits OPTN Board of Directors (BOD)-approved data elements for collection to OMB for official federal approval.

Need and Proposed Use of the Information: HRSA and the OPTN BOD use data to develop transplant, procurement, and allocation policies; to determine whether institutional members are complying with OPTN policies and HHS regulations; to determine member-specific performance; to ensure patient safety; and to fulfill the requirements of the HHS OPTN regulations at 42 CFR 121. In addition, the regulatory authority in 42 CFR 121.11 (<https://www.ecfr.gov/current/title-42/section-121.11>) requires the OPTN to maintain certain records and to make OPTN data available, consistent with applicable laws, for use by OPTN members, the Scientific Registry of Transplant Recipients, the Department of HHS, and members of the public for evaluation, research, patient information, and other important purposes.

This is a request to revise the current OPTN data collection which includes time-sensitive, life-critical data on transplant candidates and potential organ donors, the organ matching process, histocompatibility results, organ labeling and packaging, and pre- and post-transplantation data on recipients and donors. This revision also includes OPTN BOD-approved changes to the existing OMB data collection forms. The OPTN collects these specific data elements from transplant hospitals, organ procurement organizations, and histocompatibility laboratories.

HRSA and the OPTN use this information to (1) facilitate organ placement and match donor organs with recipients; (2) monitor compliance of member organizations with federal laws and regulations and with OPTN requirements; (3) review and report periodically to the public on the status of organ donation, procurement, and transplantation in the United States; (4) provide data to researchers and government agencies to study the scientific and clinical status of organ transplantation; and (5) perform transplantation-related public health surveillance, including the possible transmission of donor disease.

HRSA requests making the following changes to improve the OPTN organ matching and allocation process and improve OPTN member compliance with OPTN requirements:

1. Add two data collection forms from the OPTN Computer System (UNet platform) to the existing OMB-approved information collection.

a. The Patient Safety Contact Management form is used by OPTN members to identify the OPTN member organization's primary and secondary patient safety contact who fulfills the duties as outlined in OPTN policy 15.1.

b. The Patient Transfer form is used by transplant centers to facilitate the transfer of patients to another transplant center after transplant and throughout the annual follow-up periods.

2. Remove vascularized composite allografts (VCA) Transplant Candidate Registration. With the implementation of new VCA waitlist registration forms in the OPTN Waiting List system (in UNet), OPTN members will no longer need to validate the data on the form. The form is now read only. All changes and validations will be performed directly on the new waitlist registration forms.

3. The OPTN BOD-approved additional revisions to existing data collection forms to improve organ matching, allocation, and OPTN policy compliance.