ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Average burden per response (in hours)	Total/annual burden (in hours)
Program director survey (*Instrument 1)*	60	1	0.17	10.2
ERSEA lead staff survey (*Instrument 2)*	60	1	0.75	45
Onsite coordination [a]	60	1	1.5	90
Head Start parent/caregiver survey *(Instrument 3)*	600	1	0.5	300
Community partner survey *(Instrument 4)*	180	1	0.25	45
ERSEA lead staff focus group guide *(Instrument 5)*	24	1	1.5	36
Estimated Total Annual Burden Hours				526.2

[a] There is no instrument associated with this activity. We will ask each program director to nominate a staff person who will help coordinate data collection activities. This line accounts for the time of the onsite coordinator.

Authority: Head Start Act Section 640 [42 U.S.C. 9835].

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–10578 Filed 5–14–24; 8:45 am]

BILLING CODE 4184–22–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0026]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product; OJEMDA (tovorafenib)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that OJEMDA (tovorafenib), approved on April 23, 2024, manufactured by Day One Biopharmaceuticals, Inc., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Cathryn Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1394.

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that OJEMDA (tovorafenib), manufactured by Day One Biopharmaceuticals, Inc., meets the criteria for a priority review voucher. OJEMDA (tovorafenib) is indicated for the treatment of patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma harboring a BRAF fusion or rearrangement, or BRAF V600 mutation.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to *http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm.* For further information about OJEMDA (tovorafenib), go to the ''*Drugs@FDA*'' website at *http://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: May 9, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–10583 Filed 5–14–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2032]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Cosmetic Export Certificate Application Process

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 information collection associated with export certificate applications for FDA-regulated human food and cosmetic products.

DATES: Either electronic or written comments on the collection of information must be submitted by July 15, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 15, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered

timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment 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 comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *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 written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–N–2032 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Cosmetic Export Certificate Application Process.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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 a comment with confidential information that you do not wish to be made publicly available, submit your comments 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 comments. 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 to read background documents or the electronic and written/paper comments received, 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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Food and Cosmetic Export Certificate Application Process

OMB Control Number 0910–0793—Revision

This information collection helps support implementation of statutory and regulatory authorities governing the export of certain FDA-regulated products found in section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381), and in 21 CFR part 1, subpart E—Imports and Exports, of Agency regulations. Some countries may require manufacturers of FDA-regulated products to provide certificates for products they wish to export to that country. Accordingly, firms exporting products from the United States often ask FDA to provide such a ''certificate.'' In many cases, foreign governments are seeking official assurance that products exported to their countries can be marketed in the United States, or that they meet specific U.S. requirements. In some cases, review of an FDA export certificate may be required as part of the process to register or import a product into another country. An export certificate generally indicates that the particular product is marketed in the United States or otherwise eligible for export and that the particular manufacturer has no unresolved enforcement actions pending before, or taken by, FDA.

Consistent with this authority, interested persons may request human food and cosmetic export certificates electronically via the Export Certification Application and Tracking System (eCATS) or Certificate

Application Process (CAP), components of the FDA Industry Systems, or by contacting FDA for assistance. Health certificates are the exception and are requested via email. To facilitate the application process, we have eliminated paper-based forms. All information is currently submitted electronically using Forms FDA 3613d, 3613e, and 3613k. The eCATS Module is Form 3613k, where 3613e is the Certificate of Free Sale (*https://www.fda.gov/food/food-export-certificates/online-applications-export-certificates-food*). All ''forms'' are electronic and part of the eCATS or CAP portal accessed via *https://www.access.fda.gov.* To view representations of the forms, instructions must be downloaded and are accessible through the following links: *https://www.fda.gov/cosmetics/cosmetics-exporters/online-applications-export-certificates-cosmetics* and *https://www.fda.gov/food/food-export-certificates/online-applications-export-certificates-food.*

While burden attributable to activities associated with export certificates issued for other FDA regulated products is accounted for and approved under OMB control number 0910–0498, this collection specifically supports information collection activity attributable to export certificates issued for human food and cosmetic products. Also, because we have eliminated paper-based forms, respondents who require assistance with completing export certificate applications online may contact FDA directly by email (*CFSANExportCertification@fda.hhs.gov*) or telephone (240–402–2307). Instructions for requesting export certificates for cosmetics (Form FDA 3613d) are available online at *https://www.fda.gov/cosmetics/cosmetics-exporters/online-applications-export-certificates-cosmetics* and instructions for requesting export certificates for food (Forms FDA 3613e and Form 3613k) are available online at *https://www.fda.gov/food/food-export-certificates/online-applications-export-certificates-food.*

We are revising the information collection to include a web-based inquiry form, Form FDA 5077, entitled ''U.S. Department of Health and Human Services Food and Drug Administration Export Certification Inquiry,'' intended to facilitate processing by cross-referencing the request with existing Agency data. A mockup of the proposed electronic form is posted to the docket to solicit public comment. For food products, respondents may identify facilities using their Food Facility Registration number, FDA Establishment Identifier number, or a Data Universal Numbering System number. The system uses these identifiers to locate and auto-populate name and address information, eliminating the need for users to manually enter this information and reducing the time to complete the application. For some applications, respondents can also upload product information via a spreadsheet, which reduces the time needed to enter product information, particularly for applications that include multiple products.

Description of Respondents: The respondents to this collection of information are firms interested in exporting U.S.-manufactured human food and cosmetic products to foreign countries that require export certificates.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of certificate	Form No. [2]	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Cosmetics	FDA 3613d	66	3	198	0.5 (30 min.)	99
Food	FDA 3613e, 3613k	454	10	4,540	0.5 (30 min.)	2,270
Export Certification Inquiry	FDA 5077	520	18	9,360	0.25 (15 min.)	39
Total						2,408

[1] There are no operating and maintenance costs associated with this collection of information.
[2] All forms are submitted electronically via FDA Industry Systems.

Since our last review of the information collection, we have adjusted our estimate of the number of respondents downward. At the same time, we have increased the number of responses per respondent and added new Form FDA 5077. Cumulatively these activities result in an estimated burden increase of 39 hours and 9,360 responses annually.

Dated: May 9, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–10606 Filed 5–14–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4785]

Gina Acosta: 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) permanently debarring Gina Acosta from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Ms. Acosta was convicted of a felony under Federal law for conduct that relates to the regulation of a drug product under the FD&C Act. Ms. Acosta was given notice of the proposed debarment and an opportunity to request a hearing to show why she should not be debarred. As of March 6, 2024 (30 days after receipt of the notice), Ms. Acosta has not responded. Ms. Acosta's failure to respond and request a hearing constitutes a waiver of Ms. Acosta's right to a hearing concerning this matter.

DATES: This order is applicable May 15, 2024.

ADDRESSES: Any application by Ms. Acosta for special termination of debarment under section 306(d)(4) of the FD&C Act (21 U.S.C. 335a(d)(4)) 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