permanent residents who have experienced human trafficking, the DVHT Program. The DVHT Program includes two distinct programs: the Domestic Victims of Human Trafficking Services and Outreach Program (DVHT-SO) and the Victims of Human Trafficking in Native Communities Demonstration Program (VHT-NC). Through the DVHT Program, grant recipients provide comprehensive case management to domestic survivors of human trafficking in traditional case management and Native community settings.

OTIP proposes to continue to collect information to measure grant project performance, provide technical assistance to grant recipients, assess program outcomes, inform program evaluation, respond to congressional inquiries and mandated reports, and inform policy and program development that is responsive to the needs of victims.

The information collection captures information on participant demographics (*e.g.,* age, sex, type of trafficking experienced, service location) and services provided, along with aggregate information on outreach activities conducted, subrecipients enrolled, and dollars spent per service. Minor nonsubstantive updates have been made to performance indicators under this collection to simplify response options or to bring the collection into alignment with OTIP's grant recipient reporting database, the Anti-Trafficking Information Management System (ATIMS). Certain data element response options that do not pertain to OTIP's domestic victim service programs were removed (*e.g.,* Refugee Cash Assistance, Refugee Medical Assistance, Refugee Social Services) and certain data elements have been simplified for respondent clarity.

Respondents: DVHT Program grant recipients and clients of those programs, specifically DVHT-SO and VHT-NC funding recipients.

Annual Burden Estimates: Based on review of performance data received pertaining to the number of clients served through DVHT programs and funding levels, the total number of respondents for each form has been lowered. The time to complete each form remains the same.

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Client Characteristics and Program Entry	900	1	0.75	675	225
Client Case Closure	900	1	0.167	150.3	50.1
Barriers to Service Delivery and Monitoring	35	4	0.167	23.4	7.8
Client Service Use and Delivery	900	1	0.25	225	75
Client Outreach	35	4	0.3	42	14
Subrecipient Enrollment	35	3	0.167	17.5	5.8
Client Service Costs	35	1	0.75	26.25	8.75

Estimated Total Annual Burden Hours: 386.45.

(Authority: 22 U.S.C. 7105.)

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2025–18864 Filed 9–26–25; 8:45 am]

BILLING CODE 4184–47–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–E–5683]

Determination of Regulatory Review Period for Purposes of Patent Extension; MIPLYFFA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for MIPLYFFA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by November 28, 2025. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by March 30, 2026. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

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 November 28, 2025. 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–E–5683 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; MIPLYFFA.'' 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 § 10.20 (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: Jack Dan, Office of Regulatory Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6200, Silver Spring, MD 20993, 240–402–6940.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biological product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, MIPLYFFA (arimoclomol), indicated for use in combination with miglustat for the treatment of neurological manifestations of Niemann-Pick disease type C (NPC) in adult and pediatric patients 2 years of age and older. Subsequent to this approval, the USPTO received a patent term restoration application for MIPLYFFA (U.S. Patent No. 11,045,460) from Zevra Denmark A/S and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated March 17, 2025, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of MIPLYFFA represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for MIPLYFFA is 6,941 days. Of this time, 5,414 days occurred during the testing phase of the regulatory review period, while 1,527 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* September 21, 2005. The applicant claims May 9, 2016, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was September 21, 2005, which was 30 days after FDA receipt of an earlier IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* July 17, 2020. FDA has verified the applicant's claim that the new drug application (NDA) for MIPLYFFA (NDA 214927) was initially submitted on July 17, 2020.

3. *The date the application was approved:* September 20, 2024. FDA has verified the applicant's claim that NDA 214927 was approved on September 20, 2024.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,179 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must

contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–18786 Filed 9–26–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–5579]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and Issue Certifications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by October 29, 2025.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0750.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and Issue Certifications—21 CFR Part 1, Subpart M

OMB Control Number 0910–0750—Extension

This information collection supports FDA's Accredited Third-Party Certification Program (also referred to as the third-party food program or TPP), administered under section 808 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 384d), and codified in 21 CFR part 1, subpart M (21 CFR 1.600 through 1.725) of Agency regulations. The regulation communicates eligibility criteria, assessment standards, and establishes procedures and requirements for participation. For more information visit our website at *https://www.fda.gov/food/importing-food-products-united-states/accredited-third-party-certification-program*.

Under TPP, accreditation bodies (ABs) apply to FDA for recognition. Recognized ABs accredit third-party certification bodies (CBs) under the program, except in limited circumstances. The accredited CBs conduct food safety audits and issue food or facility certifications to eligible foreign entities. Section 808(c)(2)(B) of the FD&C Act specifies that FDA uses certifications issued by accredited CBs under TPP in deciding whether to admit certain imported food (both food for human and food for animals) into the United States that we have determined poses a food safety risk under section 801(q) of the FD&C Act (21 U.S.C. 381(q)) and in deciding whether an importer is eligible to participate in a program for expedited review and entry under section 806 of the FD&C Act (21 U.S.C. 384b). Under TPP, FDA may grant recognition of an AB for up to 5 years from the date of recognition. There are current AB participants that are recognized through fiscal year 2027 or 2028 and will need to submit renewal of recognition applications to continue their participation. Specific requirements and procedures are found in 21 CFR part 1, subpart M.

There are approximately 200,000 foreign food (both food for human and food for animals) exporters who offer their food products for import into the United States. These foreign food exporters include approximately 130,000 food production facilities and approximately 71,000 farms. A proportion of these foreign food exporters may offer food subject to mandatory certification requirements under section 801(q)(3) of the FD&C Act. In that case, to continue importing food products into the United States, eligible entities must either obtain certification from a CB accredited under TPP, or obtain certification from a foreign government designated by FDA. We assume in any given year, 75 foreign food exporters will be subject to requirements in section 801(q) of the FD&C Act.

Use of accredited CBs and food and facility certifications issued under TPP helps reduce the number of redundant audits necessary to assess compliance with food safety requirements of the FD&C Act and applicable regulations. We have developed Forms FDA 3997 and FDA 3997a to enable respondents to submit required data elements using FDA's Unified Registration Listing System (FURLS), an electronic portal (Forms FDA 3997 for ABs and 3997a for CBs) that enables respondents to complete data fields and provide information to FDA electronically. The AB and CB portals provide a standardized format for entering information, prompting respondents for input, and facilitating FDA's review of the submittal. Respondents are subject to user fees for application, renewal, and annual fees, as set forth in 21 CFR 1.700 through 1.725. The user fee rates are calculated each fiscal year and published in the **Federal Register** before the start of a new fiscal year. Electronic portal instructions and user fee information may be accessed at *https://www.fda.gov/food/importing-food-products-united-states/accredited-third-party-certification-program*.

Respondents to the collection of information are the accredited CBs that conduct audits and issue certifications to eligible entities, the ABs and CBs seeking to participate in TPP, and the recognized ABs and accredited CBs complying with the TPP requirements. An accredited CB is a foreign government, agency of a foreign government, foreign cooperative, or any other third party that a recognized AB (or, in the case of direct accreditation, FDA) has determined meets the applicable requirements of TPP and is accredited to conduct food safety audits and to issue food or facility certifications to eligible entities. An AB is an authority, such as a private third-