Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 8 U.S.C. 1522(a)(3).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–26552 Filed 12–1–23; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2564]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals, for Which Tolerances Have Been Revoked, Suspended, or Modified by the Environmental Protection Agency Pursuant to Dietary Risk Considerations

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 January 3, 2024.

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 0910–0562. 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.

Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals, for Which Tolerances Have Been Revoked, Suspended, or Modified by the Environmental Protection Agency Pursuant to Dietary Risk Considerations

OMB Control Number 0910–0562—Extension

This information collection supports FDA guidance. The Food Quality Protection Act of 1996 (Pub. L. 104–170), which amended the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (Pub. L. 80–104) and the Federal Food, Drug, and Cosmetic Act (FD&C Act), established a new safety standard for pesticide residues in food, with an emphasis on protecting the health of infants and children. The Environmental Protection Agency (EPA) is responsible for regulating the use of pesticides (under FIFRA) and for establishing tolerances or exemptions from the requirement for tolerances for residues of pesticide chemicals in food commodities (under the FD&C Act). EPA may, for various reasons, *e.g.,* as part of a systematic review or in response to new information concerning the safety of a specific pesticide, reassess whether a tolerance for a pesticide residue continues to meet the safety standard in section 408 of the FD&C Act (21 U.S.C. 346a). When EPA determines that a pesticide's tolerance level does not meet that safety standard, the registration for the pesticide may be canceled under FIFRA for all or certain uses. In addition, the tolerances for that pesticide may be lowered or revoked for the corresponding food commodities.

Under section 408(l)(2) of the FD&C Act, when the registration for a pesticide is canceled or modified due to, in whole or in part, dietary risks to humans posed by residues of that pesticide chemical on food, the effective date for the revocation of such tolerance (or exemption in some cases) must be no later than 180 days after the date such cancellation becomes effective or 180 days after the date on which the use of the canceled pesticide becomes unlawful under the terms of the cancellation, whichever is later.

When EPA takes such actions, food derived from a commodity that was lawfully treated with the pesticide may not have cleared the channels of trade by the time the revocation or new tolerance level takes effect. The food could be found by FDA, the Agency that is responsible for monitoring pesticide residue levels and enforcing the pesticide tolerances in most foods (the U.S. Department of Agriculture has responsibility for monitoring residue levels and enforcing pesticide tolerances in meat, poultry, catfish, and certain egg products), to contain a residue of that pesticide that does not comply with the revoked or lowered tolerance. We would normally deem such food to be in violation of the law by virtue of it bearing an illegal pesticide residue. The food would be subject to FDA enforcement action as an ''adulterated'' food. However, the channels of trade provision of the FD&C Act addresses the circumstances under which a food is not unsafe solely due to the presence of a residue from a pesticide chemical for which the tolerance has been revoked, suspended, or modified by EPA. The channels of trade provision (section 408(l)(5) of the FD&C Act) states that food containing a residue of such a pesticide shall not be deemed ''adulterated'' by virtue of the residue, if the residue is within the former tolerance, and the responsible party can demonstrate to FDA's satisfaction that the residue is present as the result of an application of the pesticide at a time and in a manner that were lawful under FIFRA.

To assist respondents with the information collection, we have developed the guidance document entitled ''Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals, for Which Tolerances Have Been Revoked, Suspended, or Modified by the Environmental Protection Agency Pursuant to Dietary Risk Considerations'' (May 2005). The guidance represents FDA's current thinking on its planned enforcement approach to the channels of trade provision of the FD&C Act and how that provision relates to FDA-regulated products with residues of pesticide chemicals for which tolerances have been revoked, suspended, or modified by EPA under dietary risk considerations. The guidance can be

found at the following link: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-channels-trade-policy-commodities-residues-pesticide-chemicals-which-tolerances.*

We anticipate that food bearing lawfully applied residues of pesticide chemicals that are the subject of future EPA action to revoke, suspend, or modify their tolerances, will remain in the channels of trade after the applicable tolerance is revoked, suspended, or modified. If we encounter food bearing a residue of a pesticide chemical for which the tolerance has been revoked, suspended, or modified, we intend to address the situation in accordance with provisions of the guidance. In general, we anticipate that the party responsible for food found to contain pesticide chemical residues (within the former tolerance) after the tolerance for the pesticide chemical has been revoked, suspended, or modified will be able to demonstrate that such food was handled, *e.g.,* packed or processed, during the acceptable timeframes cited in the guidance by providing appropriate documentation to FDA as discussed in the guidance document. We are not suggesting that firms maintain an inflexible set of documents where anything less or different would likely be considered unacceptable. Rather, we are leaving it to each firm's discretion to maintain appropriate documentation to demonstrate that the food was so handled during the acceptable timeframes. Examples of documentation that we anticipate will serve this purpose consist of documentation associated with packing codes, batch records, and inventory records. These are types of documents that many food processors routinely generate as part of their basic food-production operations.

Description of Respondents: The likely respondents to this collection of information are firms in the produce and food processing industries that handle food products that may contain residues of pesticide chemicals after the tolerances for the pesticide chemicals have been revoked, suspended, or modified.

In the **Federal Register** of August 2, 2023 (88 FR 50880), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received 2 comments, one of which was not PRA related and will not be addressed in this document. The other comment questioned the utility of pesticide application records used to demonstrate a pesticide was applied at an acceptable time and in a lawful manner for crops commingled with other commodities. The channels of trade provision (section 408(l)(5) of the FD&C Act) states that food containing a residue of such a pesticide shall not be deemed ''adulterated'' by virtue of the residue, if the residue is within the former tolerance, and the responsible party can demonstrate to FDA's satisfaction that the residue is present as the result of an application of the pesticide at a time and in a manner which were lawful under FIFRA. We leave it to each firm's discretion to maintain appropriate documentation to demonstrate that the food was so handled during the acceptable timeframes. Pesticide spray records may be used as a documentation to demonstrate the residues in food are from an application of the pesticide at a time and in a manner which were lawful under FIFRA.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submission of documentation	1	1	1	3	3

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We expect the total number of pesticide tolerances that are revoked, suspended, or modified by EPA under dietary risk considerations in the next 3 years to remain at a low level, as there have been no changes to the safety standard for pesticide residues in food since 1996. Thus, we expect the number of submissions we receive under the guidance document to also remain at a low level. However, to avoid counting this burden as zero, we have estimated the burden at one respondent making one submission a year for a total of one annual submission.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per record	Total hours
Develop documentation process	1	1	1	16	16

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: November 29, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–26564 Filed 12–1–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–1929]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Orphan Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 (PRA).

DATES: Submit written comments (including recommendations) on the collection of information by January 3, 2024.

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 0910–0167. Also include the FDA docket number found in brackets in the heading of this document.

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

Orphan Drugs—21 CFR Part 316

OMB Control Number 0910–0167—Extension

This information collection helps support implementation of sections 525, 526, 527, and 528 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360aa, 360bb, 360cc, and 360dd), as well as related guidance and Agency forms. Sections 525, 526, 527, and 528 of the FD&C Act pertain to the development of drugs for rare diseases or conditions, including biological products and antibiotics, otherwise known or referred to as ''orphan drugs.'' Specifically, section 525 of the FD&C Act requires written recommendations on studies required for approval of a marketing application for a drug for a rare disease or condition. Section 526 of the FD&C Act provides for designation of drugs as orphan drugs when certain conditions are met; section 527 provides conditions under which a sponsor of an approved orphan drug enjoys exclusive FDA marketing approval for that drug for the orphan indication for a period of 7 years; and, finally, section 528 is intended to encourage sponsors to make investigational orphan drugs available for treatment of persons in need on an open protocol basis before the drug has been approved for general marketing. Open protocols may permit patients who are not part of the formal clinical investigation to obtain treatment where adequate supplies exist and no alternative effective therapy is available.

Agency regulations in part 316, subpart A (21 CFR part 316, subpart A) (§§ 316.1 through 316.4) identify the scope of coverage, applicable definitions, and statutory provisions applicable to orphan drugs. The regulations in part 316, subpart B (§§ 316.10 through 316.14) set forth content and format elements for written recommendation requests and discuss FDA providing or refusing to provide the requested written recommendations. Similarly, regulations in part 316, subpart C (§§ 316.20 through 316.30) prescribe content and format elements for requesting orphan drug designation; identify submission schedules for requisite information including amendments, updates, and reports; and provide for publication and revocation of orphan drug designation. Regulations in part 316, subparts D and E (§§ 316.31 through 316.40) address orphan drug exclusive approval and open protocols for investigations, respectively. Finally, regulations in part 316, subpart F (§§ 316.50 through 316.52) provide for the issuance of guidance documents that apply to the orphan drug provisions of the FD&C Act and regulations in part 316. The list is maintained on the internet and guidance documents are issued in accordance with our good guidance practices regulation in 21 CFR 10.115, which provide for public comment at any time.

The information collection includes the Agency guidance document entitled ''Meetings with the Office of Orphan Products Development: Guidance for Industry, Researchers, Patient Groups, and Food and Drug Administration Staff'' (July 2015), available for download at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/meetings-office-orphan-products-development.* It provides recommendations to industry, researchers, patient groups, and other stakeholders interested in requesting a meeting, including a teleconference, with the Office of Orphan Products Development (OOPD) on issues related to orphan drug designation requests, humanitarian use device designation requests, rare pediatric disease designation requests, funding opportunities through the Orphan Products Grants Program and the Pediatric Device Consortia Grants Program, and orphan product patient-related topics of concern. It is also intended to assist OOPD staff in addressing such meeting requests. The guidance describes procedures for requesting, preparing, scheduling, conducting, and documenting such meetings and discusses background information we recommend be included in such requests.

The information collection includes Form FDA 3671, Common EMEA/FDA Application for Orphan Medicinal Product, and Form FDA 4035, FDA Orphan Drug Designation Request Form, intended to benefit sponsors who desire to seek orphan designation of drugs intended for rare diseases or conditions from FDA. The form is a simplified method for sponsors to provide only the information required by § 316.20 for FDA decision making. Orphan drug designation requests and related submissions (amendments, annual reports, etc.), humanitarian use device designation, and rare pediatric disease designation requests and submissions may be submitted electronically by email to the OOPD.

As communicated on our website at *https://www.fda.gov/industry/medical-products-rare-diseases-and-conditions/designating-orphan-product-drugs-and-biological-products,* respondents may submit orphan drug designation requests electronically through the Center for Drug Evaluation and Research (CDER) NextGen portal, or by emailing the required information to