

information about presubmission of promotional materials.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Limited Population Pathway for Antibacterial and Antifungal Drugs." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## II. Paperwork Reduction Act of 1995

This guidance contains no new collection of information. Therefore, additional clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521) is not required.

However, this guidance refers to previously approved FDA collections of information. These collections of information were reviewed by OMB under the PRA. The collections of information in 21 CFR part 314 for the submission of new drug applications (NDAs) under the LPAD pathway, including the submission of labeling under § 314.50(e)(2)(ii) and (l)(1)(i) and advertisements and promotional labeling under § 314.81(b)(3)(i), have been approved under OMB control number 0910–0001. The submission of biologics license applications (BLAs) under the LPAD pathway has been approved under OMB control number 0910–0338.

The submission of prescription drug labeling in 21 CFR 201.56 and 201.57 has been approved under OMB control number 0910–0572. The submission of medication guides in 21 CFR part 208 has been approved under OMB control number 0910–0393. The submission of prescription drug advertisements in 21 CFR 202.1 has been approved under OMB control number 0910–0686.

The collections of information in 21 CFR part 312, including submissions under subpart E, have been approved under OMB control number 0910–0014. The collections of information in FDA's draft guidance for industry entitled "Formal Meetings Between the FDA and Sponsors and Applicants for PDUFA Products" (available at <https://www.fda.gov/media/109951/download>), including requests for pre-NDA and pre-BLA meetings and other meetings pertaining to the LPAD pathway, have been approved under OMB control number 0910–0429.

The collections of information in FDA's final guidance for industry entitled "Expedited Programs for

Serious Conditions—Drugs and Biologics" (available at <https://www.fda.gov/media/86377/download>) have been approved under OMB control number 0910–0765.

## III. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/Drugs/Guidance/ComplianceRegulatoryInformation/Guidances/default.htm>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, or <https://www.regulations.gov>.

Dated: July 31, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2017–N–2021]

#### 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, Health and Human Services (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 September 8, 2020.

**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:

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, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@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

The Food Quality Protection Act of 1996, which amended the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) 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.

In the **Federal Register** of May 18, 2005 (70 FR 28544), we announced the availability of a final 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.” 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>.

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. 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. Accordingly, under the PRA, we are requesting the extension of OMB approval for the information collection provisions in the guidance.

*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 May 13, 2020 (85 FR 28639), we published a 60-day notice requesting public comment on the proposed collection of information. Four comments were received. Three comments offering general support for the information collection and one comment was non responsive to the information collection topics solicited. None of the comments suggested that we revise our burden estimate.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

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

<sup>1</sup> 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.

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.

We based our estimate of the hours per response on the assumption that the information requested in the guidance is readily available to the submitter. We expect that the submitter will need to gather information from appropriate persons in the submitter’s company and to prepare this information for submission to FDA. The submitter will almost always merely need to copy existing documentation. We believe that this effort should take no longer than 3 hours per submission.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Develop documentation Process .....	1	1	1	16	16

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

In determining the estimated annual recordkeeping burden, we estimated that at least 90 percent of firms maintain documentation, such as packing codes, batch records, and inventory records, as part of their basic food production or import operations. Therefore, the recordkeeping burden was calculated as the time required for the 10 percent of firms that may not be currently maintaining this documentation to develop and maintain documentation, such as batch records and inventory records. In previous information collection requests, this recordkeeping burden was estimated to be 16 hours per record. We have retained our prior estimate of 16 hours per record for the recordkeeping burden. As shown in table 1, we estimate that one respondent will make one submission per year. Although we estimate that only 1 of 10 firms will not be currently maintaining the necessary documentation, to avoid counting the recordkeeping burden for the 1 submission per year as 1/10th of a recordkeeper, we estimate that 1 recordkeeper will take 16 hours to develop and maintain documentation recommended by the guidance.

Dated: July 30, 2020.

**Lauren K. Roth,**

*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: Federal Tort Claims Act Program Deeming Sponsorship Application for Free Clinics, OMB No. 0915–0293–Revision

**AGENCY:** Health Resources and Services Administration, 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, the Health Resources and Services Administration (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 Information Collection Request must be received no later than October 5, 2020.

**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:** Federal Tort Claims Act Program Deeming Sponsorship Application for Free Clinics, OMB No. 0915–0293 – Revised

**Abstract:** Section 224(o) of the Public Health Service (PHS) Act (42 U.S.C. 233(o)), as amended, authorizes the “deeming” of certain individuals as PHS employees for the purposes of receiving liability protections, including Federal Tort Claims Act (FTCA) coverage, for the performance of medical, surgical, dental or related functions within the scope of deemed employment. Section 224(o) extends eligibility for deemed PHS employee status to free clinic health professionals including employees, officers, board members, contractors, and volunteers at qualifying free clinics. The Free Clinics FTCA Program is administered by HRSA’s Bureau of Primary Health Care. Sponsoring free clinics seeking FTCA coverage for their employees, officers, board members, contractors, and

volunteers must submit deeming applications in the specified form and manner on behalf of named individuals for review and approval, resulting in a “deeming determination” that includes associated FTCA coverage for these individuals.

HRSA is proposing several changes to the FTCA Program Deeming Applications for Free Clinics, to be used for Free Clinic deeming sponsorship applications for Calendar Year 2021 and thereafter, to improve question clarity and clarify required documentation.

Specifically, the Application includes the following proposed changes:

- Updated application language: Specifically, throughout the application, alternate terminology was utilized to provide greater clarity and specificity. These changes were based on stakeholder feedback and information received from the HRSA Health Center Program Support. These changes are not substantive in nature.
- Added Service Type and clarifications regarding professional designation: Specifically, section VI of the application was updated to include service type which will allow HRSA to verify whether an individual is performing clinical or non-clinical services. In addition to the inclusion of service type, a note was added to request that free clinics include the professional designation for each individual.

• Deleted remark in section IX: It has been determined that the information requested in this section, which related to offsite events and particularized determinations is no longer necessary to evaluate eligibility for deeming.

**Need and Proposed Use of the Information:** Deeming applications must address certain criteria required by law in order for the Secretary to deem an individual sponsored by a qualifying free clinic as a PHS employee for purposes of liability protections, including FTCA coverage. This determination cannot be made without the collection of this information. Specifically, the deeming sponsorship application form seeks information verifying that the free clinic meets the criteria to sponsor a deeming application and that the individual being sponsored is eligible to be deemed