

Estimated Total Annual Burden Hours: 1,659.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. E-mail address: OPREinfocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

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.

Dated: March 2, 2011.

Steven Hammer,

OPRE Reports Clearance Officer.

[FR Doc. 2011-5171 Filed 3-8-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Tribal Consultation Meetings

AGENCY: Administration for Children and Families' Office of Head Start (OHS), HHS.

ACTION: Notice of Tribal Consultation Meetings to be held on March 25, 2011, and April 1, 2011.

SUMMARY: Pursuant to the Improving Head Start for School Readiness Act of 2007, Public Law 110-134, notice is hereby given of one-day Tribal Consultation Sessions to be held between the Department of Health and Human Services, Administration for

Children and Families, OHS leadership, and the leadership of Tribal Governments operating Head Start (including Early Head Start) programs. The purpose of these Consultation Sessions is to discuss ways to better meet the needs of American Indian and Alaska Native children and their families, taking into consideration funding allocations, distribution formulas, and other issues affecting the delivery of Head Start services in their geographic locations [42 U.S.C. 9835, Section 640(l)(4)].

Dates & Locations: The initial 2011 OHS Tribal Consultation Sessions will be held as follows:

Friday, March 25, 2011—Rapid City, South Dakota—Best Western Ramkota.

Friday, April 1, 2011—Boston, Massachusetts—JFK Federal Building.

FOR FURTHER INFORMATION CONTACT: Camille Loya, Tribal Policy Lead, e-mail Camille.Loya@acf.hhs.gov or phone (202) 401-5964. Additional information and online meeting registration is available at <http://www.headstartresourcecenter.org>.

SUPPLEMENTARY INFORMATION: The Department of Health and Human Services announces the first 2011 OHS Tribal Consultations for leaders of Tribal Governments operating Head Start and Early Head Start programs. These Consultation Sessions will take place Friday, March 25, 2011, in Rapid City, South Dakota, and Friday, April 1, 2011, in Boston, Massachusetts. Both of these Head Start Tribal Consultation Sessions will immediately follow Department of Health and Human Services Tribal Consultations being held in Regions VIII and I, respectively.

The agendas for these initial OHS Tribal Consultations will be organized around the statutory purposes of Head Start Tribal Consultations related to meeting the needs of American Indian and Alaska Native children and families, taking into consideration funding allocations, distribution formulas, and other issues affecting the delivery of Head Start services in their geographic locations. In addition, OHS will share actions taken and in progress to address the issues and concerns raised in 2010 OHS Tribal Consultations.

Tribal leaders and designated representatives interested in submitting written testimony or proposing specific agenda topics for the Rapid City, South Dakota, or Boston, Massachusetts, Consultation Sessions should contact Camille Loya at Camille.Loya@acf.hhs.gov at least three days in advance of the Session. Proposals should include a brief description of the topic area along

with the name and contact information of the suggested presenter.

The Consultation Sessions will be conducted with elected or appointed leaders of Tribal Governments and their designated representatives [42 U.S.C. 9835, Section 640(l)(4)(A)]. Designees must have a letter from the Tribal Government authorizing them to represent the Tribe. The letter should be submitted at least three days in advance of the Consultation Session to Camille Loya at (202) 205-9721 (fax). Other representatives of Tribal organizations and Native nonprofit organizations are welcome to attend as observers.

A detailed report of each Consultation Session will be prepared and made available within 90 days of the Consultation Session to all Tribal Governments receiving funds for Head Start and Early Head Start programs. Tribes wishing to submit written testimony for the report should send testimony to Camille Loya at Camille.Loya@acf.hhs.gov either prior to the Consultation Session or within 30 days after the meeting.

Oral testimony and comments from the Consultation Session will be summarized in the report without attribution, along with topics of concern and recommendations. Hotel and logistical information for all Consultation Sessions has been sent to Tribal leaders via e-mail and posted on the Head Start Resource Center Web site at <http://www.headstartresourcecenter.org>.

Dated: March 1, 2011.

Yvette Sanchez Fuentes,

Director, Office of Head Start.

[FR Doc. 2011-5258 Filed 3-8-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0084]

Agency Information Collection Activities; Proposed Collection; 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 an

opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the 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 the information collection provisions of FDA's guidance for industry 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."

DATES: Submit either electronic or written comments on the collection of information by May 9, 2011.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>.

Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3793.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), 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.

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 (FQPA), which amended the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (the 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 (USDA) has responsibility for monitoring residue levels and enforcing pesticide tolerances in egg products and most meat and poultry products), to contain a residue of that pesticide that does not comply with the revoked or lowered tolerance. FDA 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 which were lawful under FIFRA.

In the **Federal Register** of May 18, 2005 (70 FR 28544), FDA announced the availability of a 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 the Agency'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 pursuant to dietary risk considerations. The guidance can be found at <http://www.cfsan.fda.gov/guidance.html>. FDA anticipates 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 FDA encounters food bearing a residue of a pesticide chemical for which the tolerance has been revoked, suspended, or modified, it intends to address the situation in accordance with provisions of the guidance. In general, FDA anticipates 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 the Agency as discussed in the guidance document. FDA is not suggesting that firms maintain an inflexible set of documents where anything less or different would likely be considered unacceptable. Rather, the Agency is 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 which FDA anticipates 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.

FDA is 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.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Documentation Submission	1	1	1	3	3

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

FDA expects the total number of pesticide tolerances that are revoked, suspended, or modified by EPA pursuant to 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, FDA expects the number of submissions it will receive pursuant to the guidance

document will also remain at a low level. However, to avoid counting this burden as zero, FDA has estimated the burden at one respondent making one submission a year for a total of one annual submission.

FDA based its 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 ¹

Activity	No. of record-keepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
Documentation Recordkeeping	1	1	1	16	16

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

In determining the estimated annual recordkeeping burden, FDA 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. FDA has retained its prior estimate of 16 hours per record for the recordkeeping burden. As shown in

table 1 of this document, FDA estimates that one respondent will make one submission per year. Although FDA estimates that only 1 out of 10 firms will not be currently maintaining the necessary documentation, to avoid counting the recordkeeping burden for the 1 submission per year as 1/10 of a recordkeeper, FDA estimates that 1 recordkeeper will take 16 hours to develop and maintain documentation recommended by the guidance.

Dated: March 3, 2011.
Leslie Kux,
Acting Assistant Commissioner for Policy.
 [FR Doc. 2011-5286 Filed 3-8-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0012]

Campaign To Improve Poor Medication Adherence (U18)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of the Center for Drug Evaluation and Research. A goal of the Center for Drug Evaluation and Research is to raise consumers' awareness of the