

Estimated Total Annual Burden Hours: 15,093.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. *Email address:* infocollection@acf.hhs.gov.

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project. *Fax:* (202) 395-7285. *Email:* OIRA_SUBMISSION@OMB.EOP.GOV. *Attn:* Desk Officer for the

Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2011-29811 Filed 11-17-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: State Plan for Grants to States for Refugee Resettlement.

OMB No.: 0970-0351.

Description: A State Plan is required by 8 U.S.C. 1522 of the Immigration and Nationality Act (the Act) [Title IV, Sec. 412 of the Act] for each State agency requesting Federal funding for refugee resettlement under 8 U.S.C. 524 [Title IV, Sec. 414 of the Act], including Refugee Cash and Medical Assistance, Refugee Social Services, and Targeted Assistance program funding. The State Plan is a comprehensive narrative description of the nature and scope of a States programs and provides assurances that the programs will be administered in conformity with the

specific requirements stipulated in 45 CFR 400.4-400.9. The State Plan must include all applicable State procedures, designations, and certifications for each requirement as well as supporting documentation. A State may use a pre-print format prepared by the Office of Refugee Resettlement (ORR) of the Administration for Children and Families (ACF) or a different format, on the condition that the format used meets all of the State plan requirements under Title IV of the Act and ORR regulations at 45 CFR part 400.

There is no schedule for submission of this State Plan, as all States are currently operating under an approved plan and are in compliance with regulations at 45 CFR 400.4-400.9. Per 45 CFR 400.4(b), States need only certify that the approved plan is current and continues in effect, no later than 30 days after the beginning of the Federal fiscal year. Consistent with regulations, if States wish to revise or amend the plan, a revised plan or plan amendment must be submitted to ORR as described at 45 CFR 400.7 400.9.

Respondents: State Agencies, Replacement Designees under 45 CFR 400.301(c), and Wilson-Fish Grantees (State 2 Agencies) administering or supervising the administration of programs under Title IV of the Act.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Title IV State Plan	50	1	15	750

Estimated Total Annual Burden Hours: 750.

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OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office

of Management and Budget, Paperwork Reduction Project, *Fax:* (202) 395-7285, *Email:* OIRA_SUBMISSION@OMB.EOP.GOV, *Attn:* Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2011-29820 Filed 11-17-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0492]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms

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 (the PRA).

DATES: Fax written comments on the collection of information by December 19, 2011.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, *Attn:* FDA Desk Officer, FAX: (202) 395-7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910-0633. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleston, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, (301) 796-5156, *Daniel.Gittleston@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.

Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms Classified Under 21 CFR 884.5300—(OMB Control Number 0910-0633)—Extension

Under the Medical Device Amendments of 1976 (Pub. L. 94-295), class II devices were defined as those devices for which there was insufficient information to show that general controls themselves would provide a reasonable assurance of safety and

effectiveness, but for which there was sufficient information to establish performance standards to provide such assurance.

Condoms without spermicidal lubricant containing nonoxynol-9 are classified in class II. They were originally classified before the enactment of provisions of the Safe Medical Devices Act of 1990 (Pub. L. 101-629) that broadened the definition of class II devices and now permit FDA to establish special controls beyond performance standards, including guidance documents, to help provide reasonable assurance of the safety and effectiveness of such devices.

In December 2000, Congress enacted Public Law 106-554, which among other provisions, directed FDA to “reexamine existing condom labels” and “determine whether the labels are medically accurate regarding the overall effectiveness or lack of effectiveness in preventing sexually transmitted diseases * * *.” In response, FDA recommended labeling intended to provide important information for condom users, including the extent of protection provided by condoms against various types of sexually transmitted diseases.

Respondents to this collection of information are manufacturers and repackagers of male condoms made of natural rubber latex without spermicidal lubricant. FDA expects approximately three new manufacturers or repackagers to enter the market yearly and collectively have a third-party disclosure burden of 1,224 hours. The number of respondents and prospective new manufacturers cited in table 1 of this document are based on FDA’s

database of premarket submissions. The remaining figures were derived from a study performed for FDA by Eastern Research Group, Inc., an economic consulting firm, to estimate the impact of the 1999 over-the-counter (OTC) human drug labeling requirements final rule (64 FR 13254, March 17, 1999). Because the packaging requirements for condoms are similar to those of many OTC drugs, we believe the burden to design the labeling for OTC drugs is an appropriate proxy for the estimated burden to design condom labeling.

The special controls guidance document also refers to currently approved collections of information found in FDA regulations. The collections of information under 21 CFR part 807, subpart E, have been approved under OMB control number 0910-0120; the collections of information under 21 CFR part 820 have been approved under OMB control number 0910-0073; and the collections of information in part 801 (21 CFR part 801) have been approved under OMB control number 0910-0485.

The collection of information under § 801.437 does not constitute a “collection of information” under the PRA. Rather, it is a “public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public” (5 CFR 1320.3(c)(2)).

In the **Federal Register** of July 8, 2011 (76 FR 40377), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
884.5300	3	34	102	12	1,224

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

Dated: November 14, 2011.
Leslie Kux,
Acting Assistant Commissioner for Policy.
 [FR Doc. 2011-29839 Filed 11-17-11; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0410]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Premarket Notification for a New Dietary Ingredient

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled “Premarket Notification for a New Dietary Ingredient” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-