hours (rounded to 0.37 hours), per notice 22 minutes, or 0.366 hours (rounded to 0.37 hours), per notice, for a total burden of 580,715 hours.

FDA received 16,215 cancellations of prior notices through ABI/ACS during 2007; 16,673 during 2008; and 16,045 as of August 26, 2009. Based on this experience, FDA estimates that approximately 6,500 users of ABI/ACS will submit an average of 2.64 (rounded to 3) cancellations annually, for a total of 19,500 cancellations received annually through ABI/ACS. FDA estimates the reporting burden for a cancellation submitted through ABI/ACS to be 15 minutes, or 0.25 hours, per cancellation, for a total burden of 4,875 hours.

FDA received 58,345 cancellations of prior notices through the PN System Interface during 2007; 63,779 during 2008; and 55,019 as of August 26, 2009. Based on this experience, FDA estimates that approximately 21,500 registered users of the PN System Interface will submit an average of 3.24 (rounded to 3) cancellations annually, for a total of 64,500 cancellations received annually through the PN System Interface. FDA estimates the reporting burden for a cancellation submitted through the PN System Interface to be 15 minutes, or 0.25 hours, per cancellation, for a total burden of 16,125 hours.

FDA has not received any requests for review under §§ 1.283(d) or 1.285(j) in the last 3 years (2007 through August 26, 2009); therefore, the agency estimates that one or fewer requests for review will be submitted annually. FDA estimates that it will take a requestor about 8 hours to prepare the factual and legal information necessary to prepare a request for review. Thus, FDA has estimated a total reporting burden of 8 hours.

FDA has not received any post-hold submissions under § 1.285(i) in the last 3 years (2007 through August 26, 2009); therefore, the agency estimates that one or fewer post-hold submissions will be submitted annually. FDA estimates that it will take about 1 hour to prepare the written notification described in § 1.285(i)(2)(i). Thus, FDA has estimated a total reporting burden of 1 hour.

Dated: March 11, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–5655 Filed 3–15–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0124]

Agency Information Collection Activities; Proposed Collection; Comment Request; Requirements Under the Comprehensive Smokeless Tobacco Health Education Act of 1986, as amended by the Family Smoking Prevention and Tobacco Control Act

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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information pertaining to the submission of smokeless tobacco rotational warning plans under the Comprehensive Smokeless Tobacco Health Education Act of 1986 (the Smokeless Tobacco Act), as amended by the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act).

DATES: Submit written or electronic comments on the collection of information by May 17, 2010.

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: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3794, *Jonnalynn.Capezzuto@fda.hhs.gov*.

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 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.

Requirements under the Comprehensive Smokeless Tobacco Health Education Act of 1986, as amended by the Family Smoking Prevention and Tobacco Control Act

On June 22, 2009, the President signed the Tobacco Control Act (Public Law 111–31) into law. The Smokeless Tobacco Act (15 U.S.C. 4402), as amended by section 204 of the Tobacco Control Act, requires that manufacturers, packagers, importers, distributors, and retailers (in limited circumstances) of smokeless tobacco products include one of four specified health warning label statements on product packages and in advertisements.[1] The Smokeless Tobacco Act, as amended, also requires smokeless tobacco product manufacturers, importers, distributors, and certain retailers to submit a plan to FDA specifying the method to rotate, display, and distribute the specified health warning label statements

[1] The warnings themselves disclose information completely supplied by the Federal Government. As such, the disclosure does not constitute a "collection of information" as it is defined in the regulations implementing the PRA, nor, by extension, do the financial resources expended in relation to it constitute paperwork "burden." See 5 CFR 1320.3(c)(2).

required to appear in advertising and packaging. FDA is required to review each plan submitted and approve the plan if it provides for rotation, display, and distribution of warnings in compliance with the requirements of the Smokeless Tobacco Act. To the best of FDA's knowledge, all of the affected companies have previously submitted similar plans to the Federal Trade Commission (FTC), which had authority to implement the requirements of the Smokeless Tobacco Act prior to the Tobacco Control Act's amendments. However, since the requirements of the Smokeless Tobacco Act have been revised and since FDA now has authority to implement the Smokeless Tobacco Act, each affected company will be required to submit a new plan to FDA instead of FTC. The Tobacco Control Act's amendments to the Smokeless Tobacco Act are effective on June 22, 2010.

In the **Federal Register** of August 7, 2007 (72 FR 44138), FTC published a 30-day notice announcing an opportunity for public comment and that the information collection would be sent to OMB for review. Based on FTC's previous experience with the submission of rotational plans and FDA's experience with smokeless tobacco companies (e.g., correspondence associated with user fees under section 919 of the Federal Food, Drug, and Cosmetic Act, as amended by the Tobacco Control Act), FDA estimates that there are 14 companies affected by this information collection. To account for the entry of new smokeless tobacco companies who may be affected by this information collection, FDA is estimating the total number of respondents to be 20.

When FTC originally implemented the rotational plan requirements in 1986, the Smokeless Tobacco Council, Inc. indicated that the 6 companies it represented would require 700 to 800 hours in total (133 hours each) to complete an initial rotational plan, involving multiple brands, multiple brand varieties, and multiple forms of both packaging and advertising. When FTC requested an extension of their PRA clearance in 2007, FTC decreased the estimate for submitting an initial plan from 143 hours to 60 hours, accounting for increased computerization and improvements in electronic communication over the subsequent 20 years since the Smokeless Tobacco Act was enacted. FDA believes the estimate of 60 hours to complete an initial rotational plan continues to be reasonable. However, since the requirements of the new Smokeless Tobacco Act are unfamiliar to industry, FDA is increasing the time estimate for submitting initial plans to 100 hours.

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
Submission of rotational plans for health warning label statements	20	1	20	100	2,000

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

Dated: March 11, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Availability of Final Policy Document

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Final agency guidance and response to public comments.

SUMMARY: HRSA is publishing a Final Agency Guidance ("Policy Information Notice" (PIN) 2010–01) to describe the documentation that will be considered by the Health Resources and Services Administration (HRSA) in confirming public agency status for organizations that self-identify as public agencies (also referred to in previous PINs as "public entities" or "public applicants") for Health Center Program grant funding authorized under section 330 of the Public Health Service Act, as amended, and/or for Federally Qualified Health Center Look-Alike designation. The PIN, "Confirming Public Agency Status under the Health Center Program and FQHC Look-Alike Program," and the Agency's "Response to Public Comments" are available on the Internet at *http://bphc.hrsa.gov/policy/pin1001/*and *http://bphc.hrsa.gov/policy/pin1001/PublcCommentsPIN2010–01.pdf,* respectively.

DATES: The effective date of this final Agency guidance is February 5, 2010.

Background: HRSA administers the Health Center Program, which supports more than 1,100 organizations operating more than 7,500 health care delivery sites, including community health centers, migrant health centers, health care for the homeless centers, and public housing primary care centers. Health centers serve medically underserved communities delivering preventive and primary care services to patients regardless of their ability to pay. The Health Center Program's authorizing statute and implementing regulations (Section 330 of the PHS Act, as amended, 42 CFR part 51c, and 42 CFR part 56) state that any public or non-profit private entity is eligible to apply for a grant under the Health Center Program. The term "public agency" is not defined in section 330 of the PHS Act, as amended, or in the Health Center Program's regulations; however, reference is made to public agencies in section 330 of the PHS Act, as amended, in the context of defining a public center as "a health center funded (or to be funded) through a grant under this section to a public agency." (Sentence following Section 330(k)(3)(M) of the PHS Act, as amended) HRSA is issuing this PIN to describe the documentation that will be considered by HRSA in confirming public agency status for organizations that self-identify as public agencies (also referred to in previous PINs as "public entities" or "public applicants") for Health Center Program grant funding authorized under section 330 of the Public Health Service Act, as amended, and/or for Federally Qualified Health Center Look-Alike designation.

On August 14, 2009, the Health Resources and Services Administration (HRSA) made the draft Program Information Notice (PIN), "Confirming Public Agency Status under the Health Center Program and FQHC Look-Alike Program," available for public comment. HRSA also published a notice in the