Dated: December 10, 2007.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–08–0210]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–4766 or send an e-mail to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–6974. Written comments should be received within 30 days of this notice.

Proposed Project

List of Ingredients Added to Tobacco in the Manufacture of Cigarette Products—Reinstatement with Change—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Cigarette smoking is the leading preventable cause of premature death and disability in the United States. Each year more than 440,000 premature deaths occur as the result of smoking related diseases.

The Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4401 et seq., Pub. L. 99–252) requires each person who manufactures, packages, or imports cigarettes to provide the Secretary of Health and Human Services (HHS) with a list of ingredients added to tobacco in the manufacture of cigarettes. This legislation also authorizes HHS to undertake research, and submit an annual report to Congress (as deemed appropriate) discussing the health effects of these ingredients in smokeless tobacco products. HHS has delegated responsibility for the implementation of this Act to CDC's Office on Smoking and Health (OSH). Respondents report the required information to CDC once per year according to Tobacco Ingredient and Nicotine Reporting instructions posted on the OSH web site. Changes effective with this reinstatement relate to the redesign of the OSH web site. There are no costs to respondents other than their time. The total estimated annualized burden hours are 930.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Smokeless Tobacco Manufacturers, Packagers, and Importers	143	1	6.5

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Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–08–0669]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–5960 and send comments to Maryam I. Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov.*

Comments are invited 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) ways to enhance 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. Written comments should be received within 60 days of this notice.

Proposed Project

Evaluation of State Nutrition and Physical Activity Programs to Prevent Obesity and Other Chronic Diseases—Reinstatement with Change—National Center for Chronic Disease Prevention and Health Promotion (NCCDHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description:

The ''State Nutrition and Physical Activity Programs to Prevent Obesity and Other Chronic Diseases'' (NPAO) project was established by CDC to prevent and control obesity and other chronic diseases by supporting States in the development and implementation of nutrition and physical activity interventions, particularly through population-based strategies such as policy-level changes, environmental supports and the social marketing process. The goal of the programs in this project is to attain population-based behavior change such as increased physical activity and better dietary habits; this leads to a reduction in the prevalence of obesity, and ultimately to a reduction in the prevalence of chronic diseases.

Evaluation questions for ''State Nutrition and Physical Activity Programs to Prevent Obesity and Other Chronic Diseases'' have been previously approved under OMB control no. 0920–0669, which is scheduled to expire January 31, 2008. CDC seeks OMB approval to reinstate the evaluation in 2008 with changes, in response to feedback from users and stakeholders based on experience with the previously

approved questions. The evaluation is designed to focus on the recipient activities as outlined in the original funding announcement:

- Capacity building.
- Collaboration.
- Planning.
- Monitoring the burden of obesity.
- Intervention.
- Evaluation.

Within each of these areas, the plan identifies specific evaluation questions that have been chosen for study. The evaluation questions are asked of the funded states via a web-based data collection system supported by an electronic database every 6 months during the funding cycle. The project will continue to be conducted over a 3-year period.

There are no costs to respondents except their time to participate in the survey.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
States participating in NPAO	28	2	12	672
Total				672

Dated: December 11, 2007.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0459]

International Conference on Harmonisation; Draft Guidance on Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 3 on Test for Particulate Contamination: Subvisible Particles General Chapter; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 3: Test for Particulate Contamination: Subvisible Particles General Chapter.'' The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance provides the results of the ICH Q4B evaluation of the Test for Particulate Contamination: Subvisible Particles General Chapter harmonized text from each of the three pharmacopoeias (United States, European, and Japanese) represented by the Pharmacopoeial Discussion Group (PDG). The draft guidance conveys recognition of the three pharmacopoeial methods by the three ICH regulatory regions and provides specific information regarding the recognition. The draft guidance is intended to recognize the interchangeability between the local regional pharmacopoeias, thus avoiding redundant testing in favor of a common testing strategy in each regulatory region. This is the third annex to the core Q4B guidance, which was made available in draft in the **Federal Register** of August 8, 2006 (71 FR 45059).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by February 15, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send two self-addressed adhesive labels to assist the office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: *Regarding the guidance*: Robert H. King, Sr., Center for Drug Evaluation and Research (HFD–003), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, rm. 3542, Silver Spring, MD 20993–0002, 301–796–1242; or

Christopher Joneckis, Center for Biologics Evaluation and Research (HFM–20), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–435–5681.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan,