(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.

Guidance on Reagents For Detection of Specific Novel Influenza A Viruses–21 CFR 866.3332–(OMB Control Number 0910–0584)–Extension

In accordance with section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), FDA evaluated an application for an in vitro diagnostic device for detection of influenza subtype H5 (Asian lineage), commonly known as avian flu. FDA concluded that this device is properly classified into class II in accordance with 21 U.S.C. 360c(a)(1)(B), because it is a device for which the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, but there is sufficient information to establish special controls to provide such assurance.

The statute permits FDA to establish as special controls many different things, including postmarket surveillance, development and dissemination of guidance recommendations, and ''other appropriate actions as the Secretary deems necessary'' (21 U.S.C. 360c(a)(1)(B)). This information collection is a measure that FDA determined to be necessary to provide reasonable assurance of safety and effectiveness of reagents for detection of specific novel influenza A viruses.

FDA issued an order classifying the H5 (Asian lineage) diagnostic device into class II on February 3, 2006, establishing the special controls necessary to provide reasonable assurance of the safety and effectiveness of that device and similar future devices. The new classification will be codified in 21 CFR 866.3332, a regulation that will describe the new classification for reagents for detection of specific novel influenza A viruses and set forth the special controls that help to provide a reasonable assurance of the safety and effectiveness of devices classified under that regulation. The regulation will refer to the special controls guidance document entitled ''Class II Special Controls Guidance Document: Reagents for Detection of Specific Novel Influenza A Viruses,'' which provides recommendations for measures to help provide a reasonable assurance of safety and effectiveness for these reagents.

The guidance document recommends that sponsors obtain and analyze postmarket data to ensure the continued reliability of their device in detecting the specific novel influenza A virus that it is intended to detect, particularly given the propensity for influenza viruses to mutate and the potential for changes in disease prevalence over time. As updated sequences for novel influenza A viruses become available from the World Health Organization, National Institutes of Health, and other public health entities, sponsors of reagents for detection of specific novel influenza A viruses will collect this information, compare them with the primer/probe sequences in their devices, and incorporate the result of these analyses into their quality management system, as required by 21 CFR 820.100(a)(1). These analyses will be evaluated against the device design validation and risk analysis required by 21 CFR 820.30(g), to determine if any design changes may be necessary.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section of the Federal Food, Drug, and Cosmetic Act	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Operating & Maintenance Costs
513	10	2	20	10	200	$5,000

FDA estimates that 10 respondents will be affected annually. Each respondent will collect this information twice per year, estimated to take 10 hours. This results in a total data collection burden of 200 hours (10 x 20= 200). FDA estimates that cost of developing standard operating procedures for each data collection is $500 (10 hours of work at $50/hour). This results in a total cost to industry of $5,000 ($500 x 10 respondents).

The guidance also refers to previously approved information collections found in FDA regulations. The information collections in 21 CFR part 820 have been approved under OMB control number 0910–0073.

Dated: October 5, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–24544 Filed 10–9–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–09–0469]

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) 639–5960 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) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

National Program of Cancer Registries Cancer Surveillance System (OMB no. 0920–0469 exp. Date 1/31/2010)—Revision—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In 1992, Congress passed the Cancer Registries Amendment Act, which established the National Program of Cancer Registries (NPCR). The NPCR provides support for central cancer registries (CCR) that collect, manage and analyze data about cancer cases. The NPCR-funded CCR, which are located in states, the District of Columbia, and U.S. territories, report information to CDC annually through the National Program of Cancer Registries Cancer Surveillance System (NPCR CSS) (OMB No. 0920–0469, exp. 1/31/2010). CDC plans to request OMB approval to continue collecting this information for three years.

The NPCR CSS allows CDC to collect, aggregate, evaluate and disseminate cancer incidence data at the national level, and is the primary source of information for *United States Cancer Statistics (USCS),* which CDC has published annually since 2002. The NPCR CSS also allows CDC to monitor cancer trends over time, describe geographic variation in cancer incidence throughout the country, and provide incidence data on minority populations and rare cancers. These activities and analyses further support CDC's planning and evaluation efforts for State and national cancer control and prevention. In addition, datasets can be made available for secondary analysis.

Each responding CCR is asked to report a cumulative file containing incidence data from the first diagnosis year for which the cancer registry collected data with the assistance of NPCR funds (*e.g.,* 1995) through 12 months past the close of the most recent diagnosis year (*e.g.,* 2007). Because cancer incidence data are already collected and aggregated at the State level the additional burden of reporting the information to CDC is small. Information is transmitted to CDC electronically once per year.

The Revision request will include changes. First, data definitions will be updated to reflect changes in national standards for cancer diagnosis and coding. In addition, the number of respondents will decrease. Respondents will be 45 State-based CCR, the CCR of the District of Columbia, the CCR of Puerto Rico, and the CCR that aggregates information from 10 flag territories and freely associated States in the Pacific Islands. States that receive sole funding from the National Cancer Institute are not included as respondents. The adjusted number of respondents will result in a reduction in the total estimated burden hours for the NPCR CSS. The estimated burden per response will not change.

There are no costs to respondents except their time. The total estimated annualized burden hours are 96.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Central Cancer Registries in States, Territories, and the District of Columbia	48	1	2

Dated: October 5, 2009.

Maryam I. Daneshvar,

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

[FR Doc. E9–24520 Filed 10–9–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0406]

Agency Emergency Processing Under Office of Management and Budget Review; Tobacco Product Establishment Registration and Submission of Certain Health Information; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until October 26, 2009, the comment period for the notice published in the **Federal Register** of September 1, 2009 (74 FR 45219). The document announced the proposed collection of information concerning the submission of tobacco product establishment registration and submission of certain health information, including ingredient listing and health related documents, as required by The Family Smoking Prevention and Tobacco Control Act (FSPTCA). The agency is reopening the comment period because FDA has reevaluated the expected launch date of the electronic portal and to allow interested persons additional time to review the proposed collection of information and submit comments.

DATES: Fax written comments on the collection of information by October 26, 2009. FDA is requesting approval of this emergency processing by November 2, 2009.

ADDRESSES: To ensure that comments on the information collection are received, the Office of Management and Budget (OMB) recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–5806, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–NEW. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794, e-mail: *Jonnalynn.Capezzuto@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 1, 2009 (74 FR 45219), FDA requested emergency processing of this proposed collection of information under section