The number of respondents in table 1 are the number of sponsors registered to make electronic submissions (25). The number of total annual responses is based on a review of the actual number of such submissions made between July 1, 2005, and June 30, 2006 (36 x hours per response (.08) = 2.88 total hours).

Dated: November 6, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–19044 Filed 11–8–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0183]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance on Reagents for Detection of Specific Novel Influenza A Viruses

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.

DATES: Fax written comments on the collection of information by December 11, 2006.

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: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

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.

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 section 513(a)(1)(B) of the act, 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'' (section 513(a)(1)(B) of the act). 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 control guidance document, ''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 for 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 considered comments expressed by the Centers for Disease Control and Prevention before the issuance of this guidance.

FDA also published a notice in the **Federal Register** of May 22, 2006 (71 FR 29342) soliciting comments on this information collection as required under 5 CFR 1320.8(d). In response, FDA received one comment concerning this information collection. The comment pointed out that the estimated hours per response should be closer to 15, rather than FDA's estimate of 10 hours, in order to comply with quality system regulation/document control for the new information collection. FDA agrees with this comment and as a result, the annual reporting burden hour estimate has been recalculated accordingly, i.e., the total annual reporting burden hour estimate is now 300 hours instead of 200.

Respondents to this collection of information are manufacturers of in vitro diagnostic devices.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Operating and Maintenance Costs
10	2	20	15	300	$3,500

The FDA estimates that 10 respondents will be affected annually. Each respondent will collect this information twice per year, estimated to take 15 hours. This results in a total data collection burden of 300 hours. (15 x 20 = 300). FDA estimates that cost of developing standard operating procedures for each data collection is $350 (10 hours of work at $35/hour). This results in a total cost to industry of $3,500 ($350 x 10 respondents).

Dated: November 6, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–19045 Filed 11–8–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[CGD08–06–039]

Lower Mississippi River Waterway Safety Advisory Committee

AGENCY: Coast Guard, DHS.

ACTION: Notice of meeting.

SUMMARY: The Lower Mississippi River Waterway Safety Advisory Committee (LMRWSAC) will meet to discuss various issues relating to navigational safety on the Lower Mississippi River and related waterways. The meeting will be open to the public.

DATES: The next meeting of LMRWSAC will be held on Thursday, December 14, 2006, from 9 a.m. to 12 noon. This meeting may adjourn early if all business is finished. Requests to make oral presentations or submit written materials for distribution at the meeting should reach the Coast Guard on or before December 1, 2006. Requests to have a copy of your material distributed to each member of the committee in advance of the meeting should reach the Coast Guard on or before December 1, 2006.

ADDRESSES: The meeting will be held in the Hale Boggs Building, 500 Poydras St., New Orleans, LA 70130. This notice is available on the Internet at *http://dms.dot.gov.*

FOR FURTHER INFORMATION CONTACT: Lieutenant Junior Grade (LTJG) Thao Nguyen, Assistant Committee Administrator, e-mail *thao.v.nguyen@uscg.mil.* Written materials and requests to make presentations should be mailed to Commanding Officer, USCG Sector New Orleans, Attn: Waterways Management, 1615 Poydras St, New Orleans, LA 70112.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act, Public Law 92–463; 86 Stat. 770 (5 U.S.C. App. 2).

Agenda of Meeting

Lower Mississippi River Waterway Safety Advisory Committee (LMRWSAC)

The agenda includes the following:

(1) Introduction of committee members.

(2) Opening Remarks.

(3) Approval of the April 25, 2006 minutes.

(4) Old Business:

(a) Captain of the Port status report.

(b) VTS update report.

(c) Subcommittee/Working Group update reports.

(5) New Business.

(a) New Orleans PORTS System.

(6) Adjournment.

Procedural

The meeting is open to the public. Please note that the meeting may close early if all business is finished. At the Chair's discretion, members of the public may make oral presentations during the meeting. If you would like to make an oral presentation at the meeting, please notify the Committee Administrator no later than December 1, 2006. Written material for distribution at the meeting should reach the Coast Guard no later than December 1, 2006. If you would like a copy of your material distributed to each member of the committee in advance of the meeting, please submit 25 copies to the Committee Administrator no later than December 1, 2006.

Information on Services for Individuals With Disabilities

For information on facilities or services for individuals with disabilities, or to request special assistance at the meetings, contact the Committee Administrator at the location indicated under Addresses as soon as possible.

Dated: October 23, 2006.

J.R. Whitehead,

Rear Admiral, U.S. Coast Guard, Commander, Eighth Coast Guard District.

[FR Doc. E6–18900 Filed 11–8–06; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5044–N–20]

Notice of Proposed Information Collection for Public Comment; Civil Rights Front End and Limited Monitoring Review

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments due date:* January 8, 2007.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name/or OMB Control number and should be sent to: Aneita Waites, Reports Liaison Officer, Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street, SW., Room 4116, Washington, DC 20410–5000.

FOR FURTHER INFORMATION CONTACT: Aneita Waites, (202) 708–0713, extension 4114, for copies of the proposed forms and other available documents. (This is not a toll-free number).

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended). This notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated collection techniques or other forms of information technology; *e.g.*, permitting electronic submission of responses.