334(g)), to detain during established inspections, devices that are believed to be adulterated or misbranded. FDA issued a final rule that published in a March 9, 1979, **Federal Register** (44 FR 13234) on administrative detention procedures, which includes among other things, certain reporting requirements and recordkeeping requirements under § 800.55(g) and (k), (21 CFR 800.55(g) and (k)). Under § 800.55(g), an applicant of a detention order must show documentation of ownership if devices are detained at a place other than that of the appellant. Under § 800.55(k), the owner or other responsible person must supply records about how the devices may have become adulterated or misbranded, in addition to records of distribution of the detained devices. These recordkeeping requirements for administrative detentions permits FDA to trace devices for which the detention period expired before a seizure is accomplished or injunctive relief is obtained.

FDA also has the statutory authority under section 516 of the act (21 U.S.C. 360f) to ban devices that present substantial deception or an unreasonable and substantial risk of illness or injury. The final rule for banned devices that published in the May 18, 1979, **Federal Register** (44 FR 29221) contained certain reporting requirements under 21 CFR 895.21(d) and 895.22(a). Section 895.21(d) states that if the Commissioner of Food and Drugs (the Commissioner), decides to initiate a proceeding to make a device, "a banned device," a notice of proposed rulemaking will be published in the **Federal Register** and this document will contain the finding that the device presents a substantial deception or an unreasonable and substantial risk of illness or injury. The document will also contain the reasons why the proceeding was initiated, an evaluation of data and information obtained under other provisions of the act, any consultations with the panel, and a determination as to whether the device could be corrected by labeling, change of labeling, change of advertising, and if that labeling or change of advertising has been made. Under § 895.21(d), any interested person may request an informal hearing and submit written comments. Under § 895.22, a manufacturer, distributor, or importer of a device may be required to submit to FDA all relevant and available data and information to enable the Commissioner to determine whether the device presents substantial deception, unreasonable and substantial risk of illness or injury, or unreasonable, direct, and substantial danger to the health of individuals.

During the past several years, there has been an average of less than one new administrative detention action per year. Each administrative detention will have varying amounts of data and information that must be maintained. FDA's estimate of the burden under the administrative detention provision is based on FDA's discussion with one of three firms whose devices had been detained.

In the **Federal Register** of October 16, 2009 (74 FR 53257), 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 REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
800.55(g)	1	1	1	25	25
895.21(d) and 895.22(a)	26	1	26	16	416
Totals					441

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
800.55(k)	1	1	1	20	20
Totals					461

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

Dated: January 12, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–795 Filed 1–15–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0484]

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 February 18, 2010.

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 e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0584. Also include the FDA docket number found in brackets in the heading of the document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–5156, *Daniel.Gittleson@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.

Guidance on Reagents for Detection of Specific Novel Influenza A Viruses—(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 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.

In the **Federal Register** of October 13, 2009 (74 FR 52493), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received, however it was not PRA related.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section of the Act	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
513(g)	10	2	20	15	300

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

Due to a clerical error, capital costs and operating and maintenance costs that appeared in a notice published in the **Federal Register** of October 20, 2009 (74 FR 53749) were incorrect. There are actually no capital and maintenance costs; additionally, the hours per response which were reported as 10 are actually 15. Table 1 of this document contains the correct hour burden.

Dated: January 12, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–794 Filed 1–15–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0486]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry, FDA, and Foreign Governments: Fiscal Year 2010 Medical Device User Fee Small Business Qualification and Certification

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 February 18, 2010.

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 e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0508. Also include the FDA docket number found in brackets in the heading of the document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–5156, *Daniel.Gittleson@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.

Guidance for Industry, FDA, and Foreign Governments: Fiscal Year 2010 Medical Device User Fee Small Business Qualification and Certification—OMB Control Number 0910–0508—Extension

Section 101 of the Medical Device User Fee and Modernization Act (MDUFMA) amends the Federal Food, Drug, and Cosmetic Act (the act) to provide for user fees for certain medical device applications. FDA published a **Federal Register** notice on August 3, 2009 (74 FR 38444), announcing fees for fiscal year (FY) 2010. To avoid harming small businesses, MDUFMA provides for reduced or waived fees for applicants who qualify as a "small business." This means there are two levels of fees, a standard fee, and a reduced or waived small business fee (FDA Form 3602—For Domestic Small Business Applicants For FY 2010). You can qualify for a small business fee discount under MDUFMA if you reported gross receipts or sales of no more than $100 million on your Federal income tax return for the most recent tax year. If you have any affiliates, partners, or parent firms, you must add their gross receipts or sales to yours, and the total must be no more than $100 million. If your gross receipts or sales are no more than $30 million, including all of your affiliates, partners, and parent firms, you will also qualify for a waiver of the fee for your first (ever) premarket application (product development protocol, biologics licensing application, or Premarket Report). An applicant must pay the full standard fee unless it provides evidence demonstrating to FDA that it meets the "small business" criteria. The evidence required by MDUFMA is a copy of the most recent Federal income tax return of the applicant, and any affiliate, partner, or parent firm. FDA will review these materials and decide whether an applicant is a "small business" within the meaning of MDUFMA (FDA Form 3602A— For Foreign Small Business Applicants). The 2007 Amendments provide an alternative way for a foreign business to qualify as a small business eligible to pay a significantly lower fee when a medical device user fee must be paid. Before passage of the 2007 Amendments, the only way a business could qualify as a small business was to submit a Federal (U.S.) income tax return showing its gross receipts or sales that did not exceed a statutory threshold, currently, $100 million. If a business could not provide a Federal income tax return, it did not qualify as a small business and had to pay the standard (full) fee. Because many foreign businesses have not, and cannot, file a Federal (U.S.) income tax return, this requirement has effectively prevented those businesses from qualifying for the small business fee rates. Thus, foreign governments, including the European Union, have objected. In lieu of a Federal income tax return, the 2007 Amendments will allow a foreign business to qualify as a small business by submitting a certification from its national taxing authority, the foreign equivalent of our Internal Revenue Service. This certification, referred to as a "National Taxing Authority Certification," must: Be in English; be from the national taxing authority of the country in which the business is headquartered; provide the business' gross receipts or sales for the most recent year, in both the local currency and in U.S. dollars, and the exchange rate used in converting local currency to U.S. dollars; provide the dates during which the reported receipts or sales were collected; and bear the official seal of the national taxing authority. Both FDA Forms 3602 and 3602A are available in the guidance document, "Guidance for Industry, FDA and Foreign Governments: FY 2010 MDUFMA Small Business Qualification and Certification," available on the Internet at: *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/UCM179257.pdf*.

This guidance describes the criteria FDA will use to decide whether an entity qualifies as a MDUFMA small business and will help prospective applicants understand what they need to do to meet the small business criteria for FY 2010.

The FDA Form 3602 burden is based on the number of applications received in the last 3 years. FDA believes most entities that submit FDA Form 3602A will not have any affiliates, and very few will have more than three or four affiliates. Based on our experience with FDA Form 3602A, FDA believes each business will require 1 hour to complete Sections I and II. FDA does not have any data on the time that will be required to complete Section III, the National Taxing Authority Certification, because there is a different tax verification process by each country's National Taxing Authority. The information collection for FDA Form 3602 is currently approved under OMB control