

Dated: January 12, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy,
Planning and Budget.

[FR Doc. 2010-793 Filed 1-15-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0474]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002

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 oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0510. Also include the FDA docket number found in brackets in the heading of this document.

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

Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002—(OMB Control Number 0910-0510)—Extension

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250) was signed into law on October 26, 2002. Section 201 of MDUFMA adds a new paragraph “g” to

section 704 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 374), directing FDA to accredit third parties (accredited persons) to conduct inspections of eligible manufacturers of class II or class III devices. This is a voluntary program. FDA has a guidance document that provides information for those interested in participating in this program. The guidance is entitled “Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria.”

FDA based these estimates on conversations with industry, trade association representatives, and internal FDA estimates. Once an organization is accredited, it will not be required to reapply.

In the **Federal Register** of October 22, 2009 (74 FR 54570), 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 BURDEN¹

Section of the Act	Item	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
704(g)	Request for Accreditation	3	1	3	80	240
Total Hours						240

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0475]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Administrative Detention and Banned Medical Devices

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 oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0114. Also

include the FDA docket number found in brackets in the heading of this document.

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

Administrative Detention and Banned Medical Devices—(OMB Control Number 0910-0114)—Extension

FDA has the statutory authority under section 304(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C.

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 BURDEN¹

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 BURDEN¹

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.

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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.

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