

and Cosmetic Act by adding subsection (g) (21 U.S.C. 374 (g)). This amendment authorized FDA to establish a voluntary third party inspection program applicable to manufacturers of class II or class III medical devices who meet certain eligibility criteria. On September 15, 2005, FDA issued a guidance entitled, "Requests for Inspection by an Accredited Person under the Inspection by Accredited Persons Program Authorized by Section 201 of the Medical Device User Fee and Modernization Act 2002," <http://www.fda.gov/cdrh/comp/guidance/1532.html>. This guidance describes the eligibility criteria and the process for establishments to follow when requesting FDA's approval to have an accredited person (AP) conduct a quality system regulation inspection of their establishment under the new inspection by the Accredited Persons Program (AP program) instead of FDA.

The AP program applies to manufacturers who currently market their medical devices in the United States and who also market or plan to market their devices in foreign countries. Such manufacturers may need current inspections of their establishments to operate in global commerce.

In order to meet the eligibility criteria for requesting FDA approval to have an AP conduct a quality system regulations inspection of their establishment instead of FDA, applicants must submit a request with certain information. The following information must be submitted, which shows that the applicant:

- (1) "Manufactures, prepares, propagates, compounds, or processes" class II or class III medical devices,
- (2) Markets at least one of the devices in the United States,
- (3) Markets or intends to market at least one of the devices in one or more

foreign countries when one or both of the following two conditions are met:

(a) One of the foreign countries certifies, accredits, or otherwise recognizes the selected AP applicant as a person authorized to conduct inspections of device establishments, or

(b) A statement that the law of a country where the applicant markets or intends to market the device recognizes an inspection conducted by FDA or an AP.

(4) Provided the most recent inspection performed by FDA, or by an AP under the AP program and inspection was classified by FDA as either "No Action Indicated" or "Voluntary Action Indicated" and,

(5) Provided notice advising FDA of their intent to use an AP, and identifying the AP applicant selected.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 U.S.C. Section:	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
374(g)	100	1	100	15	1,500

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

There are approximately 8,000 foreign and 10,000 domestic manufacturers of medical devices. Approximately 5,000 of these firms only manufacture class I devices and are, therefore, not eligible for the AP program. In addition, 40 percent of the domestic firms do not export devices and therefore are not eligible to participate in the AP program. Further, 10 to 15 percent of the firms are not eligible due to the results of their previous inspection. FDA estimates there are 4,000 domestic manufacturers and 4,000 foreign manufacturers that are eligible for inclusion under the AP program. Based on communications with industry, FDA estimates that on an annual basis approximately 100 of these manufacturers may submit a request to use an AP in any given year.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

Dated: May 27, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-N-0312]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Extralabel Drug Use in Animals

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for

public comment in response to the notice. This notice solicits comments on the reporting requirements associated with extralabel drug use in animals.

**DATES:** Submit written or electronic comments on the collection of information by August 4, 2008.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**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:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (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.

**Extralabel Drug Use in Animals—21 CFR Part 530 (OMB Control Number 0910-0325—Extension)**

Under part 530 (21 CFR Part 530), a veterinarian is permitted to prescribe the extralabel use of approved new animal drugs. Section 530.22 (b) of the implementing regulations permits FDA, if it finds there is a reasonable probability that the extralabel use of an animal drug may present a risk to the public health, to: (1) Establish a safe level for a residue from the extralabel use of the drug, and (2) require the development of an analytical method for

the detection of residues above that established safe level. To date, FDA has not established a safe level for a residue from the extralabel use of any new animal drug and therefore has not required the development of analytical methodology. However, the agency believes that there may be instances when analytical methodology will be required. Thus, FDA is estimating the reporting burden based on two methods being required annually. The requirement to establish an analytical method may be fulfilled by any interested person. The agency believes that the sponsor of the drug will be willing to develop the method in most cases. Alternatively, FDA, the sponsor, and perhaps a third party may cooperatively arrange for method development. The respondents may be sponsors of new animal drugs, State, or Federal government, or individuals.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
530.22(b)	2	1	2	4,160	8,320

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

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

Dated: May 27, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2008-N-0129]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Canning Establishment Registration, Process Filing, and Recordkeeping for Acidified Foods and Thermally Processed Low-Acid Foods in Hermetically Sealed Containers**

**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 July 3, 2008.

**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, or e-mailed to [baguilar@omb.eop.gov](mailto:baguilar@omb.eop.gov). All comments should be identified with the OMB control number 0910-0037. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Jenna Capezzuto, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**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.

**Food Canning Establishment Registration, Process Filing, and Recordkeeping for Acidified Foods and Thermally Processed Low-Acid Foods in Hermetically Sealed Containers—(OMB Control Number 0910-0037)—Extension**

Under the Federal Food, Drug, and Cosmetic Act (the act), FDA is authorized to prevent the interstate