Dated: April 26, 2005.

William P. Nichols,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 05–8747 Filed 5–2–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0436]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Medical Device Registration and Listing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Medical Device Registration and Listing'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 13, 2005 (70 FR 2413), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0387. The approval expires on April 30, 2008. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: April 26, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–8735 Filed 5–2–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0437]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Third-Party Review Under the Food and Drug Administration Modernization Act, Third-Party Premarket Submission Review, and Quality System Inspections Under the United States/European Community Mutual Recognition Agreement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Third Party Review Under the Food and Drug Administration Modernization Act, Third-Party Premarket Submission Review, and Quality System Inspections Under the United States/European Community Mutual Recognition Agreement'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 5, 2005 (70 FR 821), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0378. The approval expires on April 30, 2008. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: April 26, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–8736 Filed 5–2–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0157]

Agency Information Collection Activities; Proposed Collection; Comment Request; Postmarketing Adverse Drug Experience Reporting

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 postmarketing adverse drug experience reporting and recordkeeping requirements.

DATES: Submit written or electronic comments on the collection of information by July 5, 2005.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.fda.gov/dockets/ecomments*. 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: Karen L. Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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 requirement 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.

Postmarketing Adverse Drug Experience Reporting—21 CFR 310.305 and 314.80 (OMB Control Number 09109–0230)—Extension

Sections 201, 502, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321, 352, 355, and 371) require that marketed drugs be safe and effective. In order to know whether drugs that are not safe and effective are on the market, FDA must be promptly informed of adverse experiences occasioned by the use of marketed drugs. In order to help ensure this, FDA issued regulations at §§ 310.305 and 314.80 (21 CFR 310.305 and 314.80) to impose reporting and recordkeeping requirements on the drug industry that would enable FDA to take action necessary for protection of the public health from adverse drug experiences.

All applicants who have received marketing approval of drug products are required to report to FDA serious, unexpected adverse drug experiences, as well as followup reports when needed (§ 314.80(c)(1)). This includes reports of all foreign or domestic adverse experiences as well as those obtained in scientific literature and from postmarketing epidemiological/ surveillance studies. Under § 314.80(c)(2) applicants must provide periodic reports of adverse drug experiences. A periodic report includes, for the reporting interval, reports of serious, expected adverse drug experiences and all nonserious adverse drug experiences, a narrative summary and analysis of adverse drug experiences and a history of actions taken because of adverse drug experiences. Under § 314.80(i), applicants must keep for 10 years records of all adverse drug experience reports known to the applicant.

For marketed prescription drug products without approved new drug applications or abbreviated new drug applications, manufacturers, packers, and distributors are required to report to FDA serious, unexpected adverse drug experiences as well as followup reports when needed (§ 310.305(c)). Under § 310.305(f), each manufacturer, packer, and distributor shall maintain for 10 years records of all adverse drug experiences required to be reported.

The primary purpose of FDA's adverse drug experience reporting system is to provide a signal for potentially serious safety problems with marketed drugs. Although premarket testing discloses a general safety profile of a new drug's comparatively common adverse effects, the larger and more diverse patient populations exposed to the marketed drug provides, for the first time, the opportunity to collect information on rare, latent, and long-term effects. Signals are obtained from a variety of sources, including reports from patients, treating physicians, foreign regulatory agencies, and clinical investigators. Information derived from the adverse drug experience reporting system contributes directly to increased public health protection because the information enables FDA to make important changes to the product's labeling (such as adding a new warning) and when necessary, to initiate removal of a drug from the market.

Respondents to this collection of information are manufacturers, packers, distributors and applicants. 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
310.305(c)(5)	1	1	1	1	1
314.80(c)(1)(iii)	5	1	5	1	5
314.80(c)(2)	530	20	10,614	28	297,192
Total					297,198

[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 Record	Total Hours
310.305(f)	25	1	25	1	25
314.80(i)	530	1	530	1	530
Total					555

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

These estimates are based on FDA's knowledge of adverse drug experience reporting, including the time needed to prepare the reports, and the number of reports submitted to the agency during 2004.

Dated: April 26, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–8737 Filed 5–2–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0148]

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 for 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 when development of an analytical method for residue detection is required by FDA for a drug prescribed for extralabel use in animals.

DATES: Submit written or electronic comments on the collection of information by July 5, 2005.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. 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, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 4B–41, 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)

The Animal Medicinal Drug Use Clarification Act of 1994 allows a veterinarian to prescribe the extralabel use of approved new animal drugs. Also, it permits FDA, if it finds that there is a reasonable probability that the extralabel use of an animal drug may present a risk to the public health, to establish a safe level for a residue from the extralabel use of an animal drug, and to require the development of an analytical method for the detection of residues above that established safe level. Although to date, we have not established a safe level for a residue from the extralabel use of any new animal drug, and therefore have not required the development of analytical methodology, we believe that there may be instances when analytical methodology will be required. We are therefore 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. We believe 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[1]

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

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