proposed costs. In addition, the business proposal format will standardize the cost proposing and pricing process among all QIOs. With well-defined cost centers and line items, proposals can be compared among QIOs for reasonableness and appropriateness; *Form Number:* CMS–718BP, 719BP, 720BP, 721BP, SUM, STAFFING, SC1 and SC2 (OMB#: 0938–0579); *Frequency:* Reporting—Triennially; *Affected Public:* Not-for-profit institutions, Business or other for-profit; *Number of Respondents:* 20; *Total Annual Responses:* 20; *Total Annual Hours:* 455.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

Written comments and recommendations for the proposed information collections must be mailed or faxed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, New Executive Office Building, Room 10235, Washington, DC 20503. Fax Number: (202) 395–6974.

Dated: May 9, 2006.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E6–7511 Filed 5–18–06; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0180]

Agency Information Collection Activities; Proposed Collection; Comment Request; Records and Reports Concerning Experience With Approved New Animal Drugs

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 requirements for recordkeeping and reports concerning experience with approved new animal drugs. The information contained in the reports required by this regulation enables FDA to monitor the use of new animal drugs after approval and to ensure their continued safety and efficacy.

DATES: Submit written or electronic comments on the collection of information by July 18, 2006.

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, 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.

Records and Reports Concerning Experience With Approved New Animal Drugs—21 CFR 514.80—(OMB Control Number 0910–0284)—Extension

Implementation of section 512(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b) and 21 CFR 514.80 requires applicants of approved new animal drug applications and abbreviated new animal drug applications (NADAs) to submit product/manufacturing defects, initial and followup reports for adverse drug experiences and lack of effectiveness of new animal drugs, increased frequency 15-day alert reports, periodic drug experience reports (annually or semiannually in a specific format), and other reports (special drug experience reports, advertisement and promotional material submissions, and distributor statements.)

This continuous monitoring of approved NADAs affords the primary means by which FDA obtains information regarding potential problems in safety and effectiveness of marketed animal drugs and potential manufacturing problems. Current data on file with FDA is not adequate because animal drug effects can change over time, and less apparent effects may take years to manifest themselves.

Adverse reaction reports are required to be submitted by the drug manufacturer on FDA Forms 1932 or 1932a (voluntary reporting form), following complaints from animal owners or veterinarians. Also, product defects and lack of effectiveness complaints are submitted to FDA by the drug manufacturer following their own detection of a problem or complaints from product users or their veterinarians using FDA Forms 1932 and 1932a. Form FDA 2301 is used to submit the required transmittal of periodic reports and promotional material for new animal drugs. The reporting and recordkeeping burden estimates are based on the submission of reports to the Division of Surveillance, Center for Veterinary Medicine. The total annual responses are also based on the submission of reports to the Division of Surveillance, Center for Veterinary Medicine. The

annual frequency of response was calculated as the total annual responses divided by the number of respondents.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
514.80(b)(1)	1932	190	0.50	95	1	95
514.80(b)(2)(i)	1932	190	64.65	12,283	1	12,283
514.80(b)(2)(ii)	1932	190	31.62	6,007	1	6,007
514.80(b)(3)	1932	340	2.94	1,000	1	1,000
Voluntary reporting FDA Form 1932a for public	1923a	250	1	250	1	250
514.80(b)(4)	2301	190	6.45	1,226	11	13,486
514.80(b)(5)(i)	2301	190	0.13	25	2	50
514.80(b)(5)(ii)	2301	190	4.06	772	2	1544
514.80(b)(5)(iii)	2301	530	0.11	56	2	112
Total Hours						34827

[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
514.80(e)[2]	530	36.58	19,385	0.5	9,693
514.80(e)[3]	530	4.49	2,379	10.35	24,623
Total					34,316

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]Recordkeeping estimates for 514.80(b)(1), (b)(2)(i), (b)(2)(ii), (b)(3), and Form FDA 1932.
[3]Recordkeeping estimates for 514.80(b)(2)(iii), (b)(4), (c), (b)(5), and Form FDA 2301.

Dated: May 12, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–7616 Filed 5–18–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0185]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That are Not Individually Identifiable

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 guidance on informed consent for in vitro diagnostic device studies using leftover human specimens that are not individually identifiable.

DATES: Submit written or electronic comments on the collection of information by July 18, 2006.

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, 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,