will collect information several times during FY 2003 to assess the customer service provided via written responses. DBICS will conduct the written survey through mailings that will accompany actual responses. The envelopes will be sent by Release Clerks so that the actual writer has no knowledge that a particular response is being rated.; *Frequency:* Quarterly; *Affected Public:* Individuals or Households; *Number of Respondents:* 2,872; *Total Annual Responses:* 2,872; *Total Annual Hours:* 287.

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://cms.hhs.gov/regulations/pra/default.asp*, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@hcfa.gov*, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, *Attention:* Brenda Aguilar, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: February 26, 2003.

John P. Burke III,

Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances.

[FR Doc. 03–5438 Filed 3–6–03; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0063]

Agency Information Collection Activities; Announcement of OMB Approval; Consumer Surveys on Food and Dietary Supplement Labeling Issues

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Consumer Surveys on Food and Dietary Supplement Labeling Issues'' 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 Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 23, 2002 (67 FR 78234), 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 0910–0492. The approval expires on January 31, 2004. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: February 19, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03–5354 Filed 3–6–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0383]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by April 7, 2003.

ADDRESSES: Submit written comments on the collection of information to Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St., NW., rm. 10235, Washington, DC, 20503, Attention: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–26, Rockville, MD 20857, 301–827–1472.

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:

Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report—21 CFR Part 510 (OMB Control Number 0910–0012)—Extension

In response to a 60-day notice that published in the **Federal Register** of September 5, 2002 (67 FR 56846), the agency received four sets of comments. Two sets of comments were from a pharmaceutical company and two were from individuals. A discussion of the comments with the Center for Veterinary Medicine's response follows:

The two individual comments pertained to a complaint concerning a veterinary product and the elimination of antibacterial soaps. These comments are not germane to this collection of information.

Four comments pertained to the interim final rule for records and reports (21 CFR 514.80) that published February 4, 2002 (67 FR 5046), which is not the subject of this **Federal Register** notice. The closing date for receiving comments on the interim final rule was April 5, 2002. These comments were submitted on November 4, 2002 and thus, FDA will not respond. Further, the substance of these comments were submitted in response to the Interim Final Rule and will be addressed in the Final Rule for Records and Reports.

Three comments asked FDA to increase the amount of time for investigating, gathering, and processing information and data for Form FDA 1932. One comment estimated that the burden estimate should be increased by as much as 1 to 1.75 hours for product defects. Another comment estimated that the burden estimate should be increased from 0.25 to 1 hours. The third comment stated that it would take close to 2 hours to investigate, collect, conduct quality control, and record the information.

FDA will increase the burden for the Form FDA 1932 from 1 hour to 2 hours. This will increase the total burden hours for the Form FDA 1932 from 18,385 hours to 36,770 hours.

Section 512(l) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(i)), 21 CFR 510.300, 510.301, and 510.302 require that applicants of approved NADA's submit within 15-working days of receipt, complete records of reports of certain

adverse drug reactions and unusual failure of new animal drugs. Other reporting requirements of adverse reactions to these drugs must be reported annually or semi-annually in a specific format. This continuous monitoring of approved new animal drugs, affords the primary means by which FDA obtains information regarding potential problems in safety and effectiveness of marketed animal drugs and potential manufacturing problems. Data already 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. Reports are reviewed along with those previously submitted for a particular drug to determine if any change is needed in the product or labeling, such as package insert changes, dosage changes, additional warnings or contraindications, or product reformulation.

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. Likewise, 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 forms FDA Forms 1932 and 1932a. Form FDA–2301 is available for the required transmittal of periodic reports and promotional material for new animal drug applications.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Form No.	21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total hours
Form FDA 2301	510.302(a)	190	10.94	2,079	0.5	1,040
Form FDA 1932	510.302(b)	190	96.76	18,385	2.0	36,770
Form FDA 1932a (voluntary)	510.302(b)	100	1.0	100	1.0	100
Total Burden Hours						37,910

[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 of Recordkeeping	Total annual response	Hours per Recordkeeper	Total hours
510.300(a) and 510.301(a)	190	13.16	2,079	10.35	21,518
510.300(b) and 510.301(b)	190	94.74	18,385	0.50	9,193
Total Burden Hours	30,711				

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

The estimate of the times required for record preparation and maintenance is based on agency communication with industry. Other information needed to calculate the total burden hours (i.e., adverse drug reaction, lack of effectiveness, and product defect reports) are derived from agency records and experience.

Dated: February 21, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03–5355 Filed 3–6–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0302]

Agency Information Collection Activities; Announcement of OMB Approval; Guidance for Industry on Formal Meetings With Sponsors and Applicants for Prescriptions Drug User Fee Act Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Guidance for Industry on Formal Meetings with Sponsors and Applicants for Prescription Drug User Fee Act (PDUFA) Products'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Friday, October 18, 2002 (67 FR 64390), 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 0910–0429. The approval expires on February 28, 2006. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.