

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/prd/default.asp>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@hcfa.gov](mailto: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.*

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## 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.*

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## 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