

**ADDRESSES:** Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Regulatory Secretariat (VIR), General Services Administration, Room 4035, 1800 F Street, NW., Washington, DC 20405. Please cite OMB Control No. 3090-0248, Solicitation provisions and contract clauses, Placement of Orders clause, and Ordering Information clause, in all correspondence.

**SUPPLEMENTARY INFORMATION:**

**A. Purpose**

The General Services Administration (GSA) has various mission responsibilities related to the acquisition and provision of Federal Supply Service's (FSS's) Stock, Special Order, and Schedules Programs. These mission responsibilities generate requirements that are realized through the solicitation and award of various types of FSS contracts. Individual solicitations and resulting contracts may impose unique information collection and reporting requirements on contractors, not required by regulation, but necessary to evaluate particular program accomplishments and measure success in meeting program objectives.

**B. Annual Reporting Burden**

*Respondents:* 6,493.

*Hours Per Response:* .25.

*Total Burden Hours:* 1,623.

**OBTAINING COPIES OF PROPOSALS:** Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (VIR), 1800 F Street, NW., Room 4035, Washington, DC 20405, telephone (202) 208-7312. Please cite OMB Control No. 3090-0248, Solicitation provisions and contract clauses, Placement of Orders clause, and Ordering Information clause, in all correspondence.

Dated: June 24, 2005.

**Julia Wise,**

*Director, Contract Policy Division.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2004N-0515]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Medical Device Labeling Regulations**

**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 Labeling Regulations" 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 April 1, 2005 (70 FR 16824), 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 0910-0485. The approval expires on June 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: June 23, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 05-12907 Filed 6-29-05; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2004N-0558]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Evaluating the Safety of Antimicrobial New Animal Drugs With Regard to Their Microbiological Effects on Bacteria of Human Health Concerns**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the 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 August 1, 2005.

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

**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:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern (OMB Control Number 0910-0522)**

In the **Federal Register** of January 6, 2005 (70 FR 1253), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received on this information collection.

*Description:* This guidance discusses an approach for assessing the safety of antimicrobial new animal drugs with regard to their microbiological effects on bacteria of human health concern. In particular, the guidance describes methodology that sponsors of antimicrobial new animal drug applications for food-producing animals may use to complete a qualitative antimicrobial resistance risk assessment. This risk assessment should be submitted to FDA for the purposes of evaluating the safety of the new animal drug to human health. The guidance document outlines a process for integrating relevant information into an overall estimate of risk and discusses possible risk management strategies.

Table 1 of this document represents the estimated burden of meeting the reporting requirements. The burden