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.

[FR Doc. 05–12899 Filed 6–29–05; 8:45 am]

BILLING CODE 6820–61–S

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]

BILLING CODE 4160–01–S

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

estimates for these information collection requirements are based on information provided by the Office of New Animal Drug Evaluation, Center for Veterinary Medicine. The guidance document describes the type of information that should be collected by the drug sponsor when completing the antimicrobial resistance risk assessment. FDA will use the risk assessment and supporting information to evaluate the safety of original (21 CFR 514.1) or supplemental (21 CFR 514.8) NADAs for antimicrobial drugs intended for use in food-producing animals.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Antimicrobial Risk Assessments	No. of Respondents	Annual Frequency of Response	Total Annual Responses	Hours per Response	Total Hours
Hazard Identification (initial scoping of issues; relevant bacteria, resistance determinants, food products; preliminary data gathering)	15	1	15	30	450
Release Assessment (literature review; review of research reports; data development; compilation, and presentation)	10	1	10	1,000	10,000
Exposure Assessment (identifying and extracting consumption data; estimating probability of contamination on food product)	10	1	10	8	80
Consequence Assessment (review ranking of human drug importance table)	10	1	10	4	40
Risk Estimation (integration of risk components; development of potential arguments as basis for overall risk estimate)	10	1	10	12	120
Risk Management (discussion of appropriate risk management activities)	10	1	10	30	300
Total Burden					10,990

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

FDA estimates that on an annual basis an average of 15 NADAs (including original applications and major supplements) would be subject to information collection under this guidance. This estimate is based on the number of reviews completed between October 2003 and October 2004. During that period, microbial food safety for approximately 15 antimicrobial NADAs (including original and major supplements) was evaluated. This estimate excludes NADAs for antimicrobial drug combinations, generic drug applications (ANADAs), and certain supplemental NADAs.

Dated: June 23, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–12910 Filed 6–29–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2001N–0275 (formerly Docket No. 01N–0275)]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Performance Standard for Diagnostic X-Ray Systems and Their Major Components

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Performance Standard for Diagnostic X-Ray Systems and Their Major Components'' 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 June 10, 2005 (70 FR 33998 at 34012), 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 0910–0564. The approval expires on December 31, 2006. A copy of the supporting statement for