

TABLE 5.—COLLECTION OF INFORMATION REQUIRED BY CURRENT REGULATIONS AND STANDARDS—Continued

PHS Guideline Section	Description of Collection of Information Activity	21 CFR Section (Unless Otherwise Stated)
3.2.4	Procedures consistent for accreditation by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International) and consistent with the National Research Council's (NRC's) guide	AAALAC international rules of accreditation <sup>2</sup> and NRC guide <sup>3</sup>
3.2.5, 3.4, and 3.4.1	Herd health maintenance and surveillance to be documented, available, and in accordance with documented procedures; record standard veterinary care	211.100 and 211.122
3.2.6	Animal facility SOPs	PHS Policy <sup>1</sup>
3.3.3	Validate assay methods	211.160(a)
3.6.1	Procurement and processing of xenografts using documented aseptic conditions	211.100 and 211.122
3.6.2	Develop, implement, and enforce SOPs for procurement and screening processes	211.84(d) and 211.122(c)
3.6.4	Communicate to FDA animal necropsy findings pertinent to health of recipient	312.32(c)
3.7.1	PHS specimens to be linked to health records; provide to FDA justification for types of tissues, cells, and plasma, and quantities of plasma and leukocytes collected	312.23(a)(6)
4.1.1	Surveillance of xenotransplant recipient; sponsor ensures documentation of surveillance program lifelong (justify > 2 years (yrs.)); investigator case histories (2 yrs. after investigation is discontinued)	312.23(a)(6)(iii)(f) and (g), and 312.62(b) and (c)
4.1.2	Sponsor to justify amount and type of reserve samples	211.122
4.1.2.2	System for prompt retrieval of PHS specimens and linkage to medical records (recipient and source animal)	312.57(a)
4.1.2.3	Notify FDA of a clinical episode potentially representing a xenogeneic infection	312.32
4.2.2.1	Document collaborations (transfer of obligation)	312.52
4.2.3.1	Develop educational materials (sponsor provides investigators with information needed to conduct investigation properly)	312.50
4.3	Sponsor to keep records of receipt, shipment, and disposition of investigative drug; investigator to keep records of case histories	312.57 and 312.62(b)

<sup>1</sup>The "Public Health Service Policy on Humane Care and Use of Laboratory Animals" (<http://www.grants.nih.gov/grants/olaw/references/phspol.htm>).

<sup>2</sup>AAALAC international rules of accreditation (<http://www.aaalac.org/accreditation/rules.cfm>). (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site address after this document publishes in the **Federal Register**.)

<sup>3</sup>NRC's "Guide for the Care and Use of Laboratory Animals" (1996).

Dated: June 15, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2005N-0343]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Requesting an Extension to Use Existing Label Stock After the Trans Fat Labeling Effective Date of January 1, 2006**

**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 Requesting an Extension to Use Existing Label Stock After the Trans Fat Labeling Effective Date of January 1, 2006," has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Jonna Capezuto, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of April 10, 2006 (71

FR 18105), 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 0910-0571. The approval expires on May 31, 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 15, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2004D-0369]

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Recommendations for Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Recommendations for Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Jonna Capezzuto, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of February 10, 2006 (71 FR 7048), 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 0910-0583. The approval expires on April 30, 2009. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: June 15, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2005N-0457]

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Substances Generally Recognized as Safe: Notification Procedure

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Substances Generally Recognized as Safe: Notification Procedure" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Jonna Capezzuto, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of April 7, 2006 (67 FR 17892), 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 0910-0342. The approval expires on May 31, 2009. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: June 15, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2006N-0237]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Product Jurisdiction: Assignment of Agency Component for Review of Premarket Applications

**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 the procedure by which an applicant may obtain an assignment or designation determination.

**DATES:** Submit written or electronic comments on the collection of information by August 21, 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:** Jonna Capezzuto, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**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