

The burden estimate for this collection of information is based on agency records and experience over the past 3 years. Agency personnel handling the petitions for administrative reconsideration of an action estimate approximately 12 requests being received by the agency annually, each requiring an average of 10 hours preparation time.

Dated: September 19, 2000.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning, and Legislation.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 00N-0726]

#### **Agency Information Collection Activities; Announcement of OMB Approval; General Licensing Provisions: Changes to an Approved Application, Labeling, and Revocation and Suspension**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "General Licensing Provisions: Changes to an Approved Application, Labeling, and Revocation and Suspension" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of June 20, 2000 (65 FR 38290), 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 0910-0315. The approval expires on August 31, 2003. A

copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: September 19, 2000.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning, and Legislation.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 00N-1359]

#### **Agency Information Collection Activities; Submission for OMB Review; Comment Request; Affirmation of Generally Recognized as Safe (GRAS) Status**

**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.

**DATES:** Submit written comments on the collection of information by October 25, 2000.

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

**FOR FURTHER INFORMATION CONTACT:** Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**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.

#### **Affirmation of Generally Recognized As Safe (GRAS) Status (21 CFR 170.35(c)(1)) (OMB Control Number 0910-0132)—Extension**

Under the authority of sections 201, 402, 409, and 701 of the Federal Food,

and Cosmetic Act (the act) (21 U.S.C. 321, 342, 348, and 371), FDA reviews petitions for affirmation as GRAS that are submitted on a voluntary basis by the food industry and other interested parties. Under section 409 of the act, the agency has the authority to regulate food additives. Section 201(s) of the act defines "food additive" and expressly excludes from the definition substances GRAS for use in food.

Specifically under section 201(s) of the act, a substance is GRAS if it is generally recognized among experts qualified by scientific training and experience to evaluate its safety, to be safe through either scientific procedures or common use in food. The act has historically been interpreted to permit food manufacturers to make their own determination that use of a substance in food is GRAS. To implement the GRAS provisions of the act, FDA has issued procedural regulations under § 170.35(c)(1) (21 CFR 170.35(c)(1)). These regulations establish a process by which a person may obtain FDA concurrence with a GRAS determination; this concurrence is referred to as "GRAS affirmation." These regulations set forth the information to be submitted to FDA to obtain agency concurrence that a substance is GRAS (§ 170.35(c)(1)).

GRAS petitions are reviewed by FDA to ascertain whether the available data establish that the intended use of the substance is GRAS based upon either a history of the safe use of the substance, or upon widely available safety data (scientific procedures). The GRAS affirmation process is a voluntary one, and there is some risk that FDA may not agree with the petitioner's GRAS determination. The GRAS petition process does provide a public procedure for coordinating GRAS determinations. The process reduces the potential for public health problems when substances are marketed based upon unwarranted safety determinations and allows a food manufacturer to rely on the lawful status of a substance that has been affirmed by FDA as GRAS.

In the **Federal Register** of July 5, 2000 (65 FR 41472), the agency requested comments on the proposed collection of information. No comments were received.

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