

Dated: October 20, 1999.

**William K. Hubbard,**

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

[FR Doc. 99-27974 Filed 10-26-99; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 99N-1393]

#### Agency Information Collection Activities; Announcement of OMB Approval; State Petitions for Exemption from Preemption

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "State Petitions for Exemption from Preemption" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**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 the **Federal Register** of August 20, 1999 (64 FR 45554), 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 0910-0277. The approval expires on October 31, 2002. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: October 20, 1999.

**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. 99N-1522]

#### Agency Information Collection Activities; Announcement of OMB Approval; Temporary Marketing Permit Applications

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Temporary Marketing Permit Applications" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**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 the **Federal Register** of August 31, 1999 (64 FR 47508), 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 0910-0133. The approval expires on October 31, 2002. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: October 20, 1999.

**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. 99N-4397]

#### Agency Emergency Processing Request Under OMB Review; Survey of Food Manufacturing Facilities for Year 2000 Compliance

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information concerns a survey of food manufacturing facilities for Year 2000 compliance.

**DATES:** Submit written comments on the collection of information by November 1, 1999.

**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: Desk Officer for FDA. All comments should be identified with the docket number found in brackets in the heading of this document.

**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:** Section 705(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 375(b)) permits the Secretary of Health and Human Services (the Secretary) to disseminate information regarding food, drugs, devices, and cosmetics in situations involving in the opinion of the Secretary imminent danger to health, or gross deception of the consumer. FDA has requested emergency processing of this proposed collection of information under the PRA (44 U.S.C. 3507(j) and 5 CFR 1320.13). FDA is requesting certain information, i.e., manufacturer, food products produced, etc., immediately to allow for the assessment of their vulnerability to Year 2000 problems and to take corrective actions, if necessary, in advance of January 1, 2000. The potential existence of Year 2000 problems in the food industry could pose potentially serious health and safety consequences. The use of normal clearance procedures would prolong the time needed to assess Year 2000 compliance by regulated industry.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and

clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Title: Survey of Food Manufacturing Facilities for Year 2000 Compliance**

Facilities will be asked to provide a status on their Year 2000 readiness.

They will also be asked if they have contingency plans. The survey will also ask if they have tested, verified, and certified their systems. The request will also ask for a single point of contact at the manufacturer to discuss information.

The manufacturer will provide paper copy of the information to FDA. The provision of information will signify that the information provided is true to

the best of the manufacturer's knowledge. The information will be used for possible FDA inspectional followup, if it indicates potential unsafe food manufacturing situations, as well as in the preparation of industry and consumer directed material addressing Year 2000 concerns.

*Respondents:* Food manufacturers.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
250	1	250	1	250

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA establishment inventory lists were used to determine the number of firms who would be subject to this collection. FDA estimates that it will take firms an average of 2 hours to collect, prepare, and submit the requested information.

Dated: October 20, 1999.

**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. 95F-0187]

**Ciba Specialty Chemicals Corp.;  
Withdrawal of Food Additive Petition**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 5B4467) (filed by Ciba Specialty Chemicals Corp.; formerly named Ciba-Geigy Corp.) proposing that the food additive regulations be amended to provide for the safe use of poly[[6-[(1,1,3,3-tetramethylbutyl)amino]-s-triazine-2,4-diyl] [2,2,6,6-tetramethyl-4-piperidyl]imino] hexamethylene [(2,2,6,6-tetramethyl-4-piperidyl)imino]] as a light stabilizer in polymers used as indirect food additives.

**FOR FURTHER INFORMATION CONTACT:**

Julius Smith, Center for Food Safety and Applied Nutrition (HFS-215), Food and

Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3091.

**SUPPLEMENTARY INFORMATION:** In a notice published in the **Federal Register** of August 3, 1995 (60 FR 39753), FDA announced that a food additive petition (FAP 5B4467) had been filed by Ciba-Geigy Corp., Seven Skyline Dr., Hawthorne, NY 10532. The petition proposed to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the safe use of poly[[6-[(1,1,3,3-tetramethylbutyl)amino]-s-triazine-2,4-diyl] [2,2,6,6-tetramethyl-4-piperidyl]imino] hexamethylene[(2,2,6,6-tetramethyl-4-piperidyl)imino]], as a light stabilizer in polymers used as an indirect food additive. Ciba Specialty Chemicals Corp., has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: October 12, 1999.

**Alan M. Rulis,**

*Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket Nos. 99D-4488 and 99D-4489]

**Guidance for Industry: Reducing Microbial Food Safety Hazards for Sprouted Seeds and Guidance for Industry: Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing two related guidance documents entitled "Guidance for Industry: Reducing Microbial Food Safety Hazards for Sprouted Seeds" and "Guidance for Industry: Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production." These guidances are intended to provide recommendations to suppliers of seed for sprouting and sprout producers about how to reduce microbial food safety hazards common to the production of raw sprouts to ensure that sprouts are not a cause of foodborne illness and to ensure that they comply with the food safety provisions of the Federal Food, Drug, and Cosmetic Act (the act). The first guidance is based largely on recommendations from the National Advisory Committee for Microbiological Criteria for Food's report entitled "Microbial Safety Evaluations and Recommendations on Sprouted Seeds" (the 1999 NACMCF report) (Ref. 1). The second guidance is intended to assist sprouters in implementing one of the principle recommendations (i.e., microbial testing) in the broader sprout guidance.

**DATES:** Written comments may be submitted at any time, however, comments should be submitted by December 13, 1999, to ensure adequate consideration in preparation of revised documents, if warranted.

**ADDRESSES:** Submit written requests for single copies of the guidance entitled "Guidance for Industry: Reducing Microbial Food Safety Hazards for Sprouted Seeds" and/or the guidance entitled "Guidance for Industry: Sampling and Microbial Testing of