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.

Use of Impact-Resistant Lenses in Eyeglasses and Sunglasses (OMB Control Number 0910–0182)—Extension

Under section 519 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(i)), every manufacturer or importer of a device intended for human use shall establish and maintain records. This regulation is designed to protect the eyeglass and sunglass wearer from potential eye injury resulting from shattering of ordinary eyeglass lenses, and it requires that eyeglasses and sunglasses be fitted with impact-resistant lenses. Section 801.410(f) (21 CFR 801.410(f)) requires that the results of impact tests and description of the test method and apparatus also be kept for a period of 3 years. These records are valuable to FDA when investigating eye injury complaints.

The expected respondents to this collection are manufacturers of impact-resistant lenses. FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
801.410(f)	30	769,000	23,070,00	.0008	18,456

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

The Vision Council of America (www.visionsite.org) provided sales figures that were used in estimating the burden for this collection. Beginning in 1998, a growth rate of 2.6 percent for the distribution of lenses began, and it was assumed that this growth rate continued in 1999 and 2000. This resulted in an increase in the number of eyeglasses shipped annually to 89 million lenses shipped by year 2000.

By also assuming that the glass/plastic lenses-produced ratio remained as in previous years (22 percent glass and 78 percent plastic), that glass lenses must be tested individually, and only 5 percent of the plastic lenses must be tested, then 23,070,000 lenses should be tested. This figure was derived by taking 22 percent of 89 million glass lenses (19,600,000) and adding it to 5 percent of the remaining plastic lenses (5 percent x 69,400,000 = 3,470,000).

Next, divide the total tests (23,070,000) by 30 manufacturers to return the annual frequency of recordkeeping figure of 769,000. Previously, FDA and industry experts estimated that on average, each test could be completed and recorded in 3 seconds. Industry, therefore, could complete 1,200 tests per hour. Therefore, it is estimated that the total burden for this collection is 19,225 hours, which is calculated by taking the total records figure (23,070,000) and dividing it by tests per hour (1,200). The total hours was calculated by multiplying the total number of records (23,070,000) and the hours per record (.0008).

There is no burden estimated for maintaining sale or distribution records under § 801.410(e) since firms are retaining their records as a normal and customary business practice for reasons of product liability.

Dated: November 20, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95N–0220]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Substances Approved for Use in the Preparation of Meat and Poultry Products

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 December 28, 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.

Petition for Approval of Substances for Use in the Preparation of Meat and Poultry Products—21 CFR 71.1 and 171.1

Sections 409 and 721 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348 and 379e) require FDA to evaluate the safety and regulate the use of food and color additives used as ingredients in or on all foods. These sections also authorize FDA to accept petitions for approval of food and color additives. The Federal Meat Inspection Act and the Poultry Products Inspection Act (21 U.S.C. 601(m)(2) and 453(g)(2), respectively) authorize the administration of the Food Safety and Inspection Service (FSIS), U.S. Department of Agriculture to determine the suitability of the use of a substance in meat and poultry products. Regulations of the two agencies regarding petition submissions at times include conditions, formats, and terms that are not fully consistent with one another because of the different statutory mandates. Under the current process, FDA and FSIS conduct separate, sequential reviews of petitions, each agency applying its respective

procedures to ascertain that a substance is lawful for the use intended in or on products containing meat or poultry.

When petitioning for approval for the use of substances in meat and poultry products, the applicants must provide four copies of the petition to FDA, rather than the three copies as currently specified in §§ 71.1 and 171.1 (21 CFR 71.1 and 171.1). FDA will then forward a copy of the petition or relevant portions of the petition to FSIS so that both agencies can perform the necessary reviews simultaneously, thus reducing the time it takes to authorize an ingredient for use in meat and poultry products. The petitioners are not required to submit any new information to either FDA or FSIS.

This regulation results from a coordinated effort by the two agencies to ease the paperwork burden on regulated industries through streamlining the Federal Government's food ingredient approval process for substances used in meat and poultry products.

Description of Respondents: Businesses or other for profit.

In the **Federal Register** of August 25, 2000 (65 FR 51758), 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:

TABLE 1.—ESTIMATED ANNUAL INCREASE IN REPORTING HOUR BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Increase in Hours per Response	Total Increase in Hours
71.1 and 171.1	10	1	10	2	20

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

Based on FDA's past experience with food and color additive petitions and on discussions with FSIS about its past experience, it will receive 10 petitions annually that request approval for use of a substance in meat and poultry products. Submission of a petition for the use of a substance in meat and poultry products is a one-time event. FDA estimates that the respondent would expend 2 hours to make a fourth photocopy of the petition, necessary for FDA to send to FSIS to conduct a simultaneous review. FDA, therefore, estimates that the total burden of data collection under §§ 71.1 and 171.1 will increase by 20 hours per year because of the requirement to submit a fourth copy of petitions when a substance is to be used in meat or poultry products.

Dated: November 20, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–30330 Filed 11–27–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 82F–0349, 90F–0188, 91F–0169, 93F–0157, 93F–0199, 95F–0011, 96F–0032, 96F–0223, 98F–0226, 98F–0288, 98F–0289, 99F–0052, 99F–0460, 99F–1074, 99F–2244, 99F–2245, 99F–5012, and 00F–0089]

Withdrawal of Food Additive Petitions Subsequently Converted to Food Contact Notifications

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 18 food additive petitions proposing that the food additive regulations be amended to provide for the safe use of certain new food additives. The petitioners subsequently requested that their petitions be converted to food-contact notifications for review under the agency's new premarket notification (PMN) program for food-contact substances. The requested uses are now the subjects of effective notifications.

FOR FURTHER INFORMATION CONTACT: Sylvia D. Dodson, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3087.

SUPPLEMENTARY INFORMATION: In notices published in the **Federal Register** on the dates indicated in the table below, FDA announced the filing of 18 food additive petitions. These petitions proposed to amend the food additive regulations in the sections listed in the table to provide for the safe use of the listed substances intended for use in food-contact articles. Since publication of these filing notices, the petitioners have requested that their respective petitions be converted to food-contact notifications for review under the agency's new PMN process for food-contact substances and that their petitions be withdrawn when the corresponding notifications become effective. These petitions were converted to notifications and subsequently reviewed under the PMN process. The requested uses are now the subjects of effective notifications. The corresponding food additive petitions are now withdrawn without prejudice to a future filing (21 CFR 171.7).

TABLE 1.

FAP No.[1] and Docket No.	FNC No.[2]	FR Citation and Date	Company	Section/Part	Additive	Use
3B4354, 93F–0199	28	59 FR 59410, Nov. 17, 1994	Asahi Chemical Industry Co., Ltd., c/o Regulatory Assistance Corp.	175.105 and 177.1810	Maleic anhydride modified hydrogenated styrene butadiene block polymer.	Not Specified.
7A4539, 98F–0226	31	63 FR 18921, Apr. 16, 1998	Nalco Chemical Co.	173.310	Disodium or dipotassium fluorescein.	In boilers where steam may contact food.