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.

User Fee Cover Sheet; Form FDA 3397—(OMB Control Number 0910–0297)—Extension

Under sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g and 379h), the ''Prescription Drug User Fee Act of 1992'' (PDUFA) (Public Law 102–571), as amended by the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115), FDA has the authority to assess and collect user fees for certain drug and biologics license applications and supplements. Under this authority, pharmaceutical companies pay a fee for certain new human drug applications, biologics license applications or supplements submitted to the agency for review. Because the submission of user fees concurrently with applications and supplements is required, review of an application cannot begin until the fee is submitted. Form FDA 3397 is the user fee cover sheet, which is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to account for and track user fees. The form provides a cross-reference of the fee submitted for an application with the actual application by using a unique number tracking system. The information collected is used by FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of new drug applications, biologics license applications, and supplemental applications.

Respondents to this collection of information are new drug and biologics manufacturers. Based on FDA's data base system, there are an estimated 208 manufacturers of products subject to PDUFA. However, not all manufacturers will have any submissions in a given year and some may have multiple submissions. The total number of annual responses is based on the number of submissions received by FDA in fiscal year 1999. CDER estimates 2,478 annual responses that include the following: 125 new drug applications, 1,458 chemistry supplements, 755 labeling supplements, and 140 efficacy supplements. CBER estimates 443 annual responses that include the following: 8 biologics license applications, 396 manufacturing (chemistry) supplements, 29 labeling supplements and 10 efficacy supplements. The estimated hours per response are based on past FDA experience with the various submissions, and range from 5 to 30 minutes. The hours per response are based on the average of these estimates.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA 3397	208	14.4	2,921	0.30	876

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

Dated: August 11, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–21011 Filed 8–17–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1246]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Food Safety Survey

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 September 18, 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.

Food Safety Survey (OMB Control Number 0910–0345)—Extension

Under section 903(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(b)(2)), FDA is authorized to conduct research relating to foods and to conduct educational and public information programs relating to the safety of the nation's food supply. FDA is planning to conduct a consumer survey about food safety under this authority. The food safety survey will provide information about consumers' food safety awareness, knowledge, concerns, and practices. A nationally representative sample of 2,000 adults in households with telephones and cooking facilities will be selected at random and interviewed by telephone. Participation will be voluntary. Detailed information will be obtained about risk perception, perceived sources of food contamination, knowledge of particular microorganisms, safe care label use, food handling practices, consumption of raw foods from animals, information sources, and perceived foodborne illness and food allergy experience.

Most of the questions to be asked are identical to ones asked in the 1998 Food Safety Survey. Because of recent national consumer education campaigns about food safety and the large amount of media attention to food safety issues

in the past few years, consumer attitudes, knowledge, and practices are likely to have changed greatly since the 1998 survey. FDA needs current information to support consumer education programs and regulatory development. In addition, FDA needs information from the consumer perspective on several new areas related to food safety. New areas include attitudes toward: Genetically modified foods, irradiated foods, and organically grown foods; handling of leftovers and foods associated with *listeria monocytogenes* contamination; washing practices for fresh fruits and vegetables; reaction to warning statements on unpasteurized juice and to handling statements on eggs; disability status; and perceived food allergy.

In the **Federal Register** of May 2, 2000 (65 FR 25491), the agency requested comments on the proposed collection of information. Four comments were received. All comments responded to the third statement on which FDA invited comments: Ways to enhance the quality, utility, and clarity of the information to be collected.

Two comments were related to the questions about irradiation of food, one from a consumer group, and the other from industry. One comment does not want the survey to imply that all irradiated food is required to be labeled. It states that FDA misleads consumers when it states or implies that irradiated foods are labeled, because irradiated foods intended for further processing or cooking are not labeled at the consumer level, and herbs, spices, and some seasonings are never labeled.

The second comment urges FDA to include additional questions to probe consumer attitudes on irradiation and the irradiation label, given the changes in this arena in the past few years. One example provided is approval and marketing of irradiated meat, and the positive media coverage of this process. It provides a specific question from the literature and points out that if we ask the same question, we would have a comparison over time. The question would follow the current question measuring perceived safety of irradiated foods. That specific question is this: ''Irradiation has been approved as safe by the U.S. Food and Drug Administration. How does this affect your opinion?'' (Answers: less concerned, same opinion, or more concerned.)

Both comments were concerned about the placement of the irradiation questions, immediately after a section on food safety problems and in a section of perceived sources of contamination. One states that such placement might lead consumers to think that FDA has doubts of the safety of irradiation. It recommends placing the irradiation questions in the section on cooking and other methods to control foodborne pathogens. Both comments asked that FDA publish or provide them with a final copy of the survey.

The agency is not persuaded that the comment about labeling of irradiated food is germane to the survey because none of the questions on the survey mention labeling of irradiated foods; the labeling aspect of the irradiation issue is beyond the scope of the survey.

The agency is not persuaded that the specifically recommended question is appropriate in the context of the current survey; such detailed attitude questions are beyond the scope of the data collection objectives. However, the comment requesting that additional questions be asked about irradiated foods raises the issue of whether FDA will obtain sufficient information from the current questions. Analysis of the current question will provide certain detailed information. For example, the distribution of characteristics and of information sources of those who have given beliefs about irradiated foods can be compared with the distributions of those with more or less food safety knowledge, as measured in other sections. The agency is exploring whether its information needs require further questions about consumers' prior knowledge and assumptions. Any additional questions will be determined in time to incorporate them into the final questionnaire, along with any other changes required by comments to this notice.

The agency agrees that the irradiated questions are better asked in a different section; they will be moved to follow Section K of the questionnaire entitled ''Information Sources''. The agency will provide a copy of the final survey to all interested parties who so request.

Another comment urges FDA to use the survey to address the issue of consumer misinformation regarding organic foods. The comment is concerned that Americans are misled by organic labels, and in particular will be misled by the United States Department of Agriculture (USDA) organic seal, to believe that organic foods are safer, more nutritious, or otherwise better in some way than conventional foods.

Testing of any specific label statements is outside the scope of the survey, and gathering specific information about the USDA seal for organic foods is inappropriate at this time, before the seal has been finalized. However, like the request for more information about consumer understanding of irradiated foods, this comment raises the issue of whether the agency will obtain sufficient information about consumers' knowledge and assumptions related to organic foods, and the agency has a similar response. FDA plans to perform analysis of the organic foods questions that will provide detailed information about certain aspects of consumer knowledge and information sources. In light of the comment, the agency is exploring whether its information needs require further questions about consumers' prior knowledge and assumptions, and any additional questions will be incorporated into the final questionnaire along with any other changes required by comments to the 30-day notice.

One comment is concerned about the list of foods that form the response to several questions, including the questions that ask what kinds of food the respondent thought were related to contamination by particular micro-organisms, and, in the 1998 survey, to the question on foods the respondent thinks of as high risk for food poisoning. The concern is that the inclusion of ''mayonnaise or salads made with mayonnaise'' will perpetuate the ''mayo myth'' that mayonnaise is a high risk food. The comment approves of the question about eating raw eggs that clearly distinguishes homemade mayonnaise from commercial mayonnaise.

FDA is very much aware that commercial mayonnaise is not a high food safety risk, and it is not treated as such in the survey. The comment mistakenly assumed that the precoded list of foods that follows several questions is read to the respondent, when it is not read. The list is seen only by the interviewers, who need it in order to code the response. ''Mayonnaise or salads made with mayonnaise'' is included as a possible response because some consumers maintain the view that this type of food is high risk. Over time, FDA will be able to track whether this myth is diminishing. Meanwhile, commercial mayonnaise will not be maligned in the survey. It is important to keep the item in the list so that consumer beliefs about commercial mayonnaise can be measured. As the comment notes, when mayonnaise is mentioned to respondents (as in the eating raw egg question), a distinction is made between homemade and commercial mayonnaise.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
2,000	1	2,000	.5	1,000

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

The burden estimate is based on FDA's experience with the 1998 survey mentioned in the previous paragraph.

Dated: August 11, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–21007 Filed 8–17–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00C–1444]

FEM, Inc.; Filing of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that FEM, Inc., has filed a petition proposing that the color additive regulations be amended to eliminate the limitation on the amount of silver used as a color additive in fingernail polish.

FOR FURTHER INFORMATION CONTACT: James C. Wallwork, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3078.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 721(d)(1) (21 U.S.C. 379e(d)(1))), notice is given that a color additive petition (CAP 0C0272) has been filed by FEM, Inc., 1521 Laguna St. #210, Santa Barbara, CA 93101. The petition proposes to amend the color additive regulations in § 73.2500 *Silver* (21 CFR 73.2500) to eliminate the limitation on the amount of silver used as a color additive in fingernail polish.

The agency has determined under 21 CFR 25.32(r) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: August 1, 2000.

Alan M. Rulis,

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

[FR Doc. 00–21012 Filed 8–17–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 93F–0360]

Cognis Corporation; 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 3B4400) proposing that the food additive regulations be amended to provide for the safe use of pentaerythritol mixed esters of $C_{16–18}$ fatty acids as a dispersant for titanium dioxide in polyethylene, polypropylene, and polystyrene intended for contact with food.

FOR FURTHER INFORMATION CONTACT: Vivian M. Gilliam, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3094.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of October 29, 1993 (58 FR 58172), FDA announced that a food additive petition (FAP 3B4400) had been filed by Henkel Corporation, 300 Brookside Ave., Ambler, PA 19002–3498. The petition proposed to amend the food additive regulations to provide for the safe use of pentaerythritol mixed esters of $C_{16–18}$ fatty acids as a dispersant for titanium dioxide in polyethylene, polypropylene, and polystyrene intended for contact with food. Henkel Corporation has since changed its name to Cognis Corporation. Cognis Corporation has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: August 1, 2000.

Alan M. Rulis,

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

[FR Doc. 00–21008 Filed 8–17–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F–1193]

Troy Corporation; 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 7B4533) proposing that the food additive regulations be amended to provide for the safe use of 3–iodo–2–propynyl butyl carbamate as a fungicidal additive for wood products intended to contact food.

FOR FURTHER INFORMATION CONTACT: Mark A. Hepp, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3098.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of December 24, 1998 (63 FR 71295), FDA announced that a food additive petition (FAP 7B4533) had been filed by Troy Corporation, c/o S.L. Graham & Associates, 1801 Peachtree Lane, Bowie, MD 20721. The petition proposed to amend the food additive regulations in § 178.3800 *Preservatives for wood* (21 CFR 178.3800) to provide for the safe use of 3-iodo-2-propynyl butyl carbamate as a fungicidal additive for wood products intended to contact food. Troy Corporation has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: July 26, 2000.

Alan M. Rulis,

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

[FR Doc. 00–21057 Filed 8–17–00; 8:45 am]

BILLING CODE 4160–01–F