

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
314.97	7	1	7	160	1,120 ²
314.70	2	1	1	20	40 ³
Total					1,160

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

² Reporting burden for manufacturers of nonsterile products.

³ Reporting burden for manufacturers of sterile products.

Because of the estimated increase from the proposed rule to the final rule in the number of respondents for nonsterile products, the number of recordkeepers in the recordkeeping burden of Table 2 has increased by two from the proposed rule. FDA estimated

a total of seven recordkeepers in the proposed rule and now estimates a total of nine recordkeepers as a result of new data collected by ERG. The proposed rule estimated 2 hours per record, and FDA's review of that estimate and its experience with the control and

validation of microbiological contamination supports this proposed estimate. Therefore, the total number of hours for the recordkeeping burden has increased from 14 hours to 18 hours.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
211.113(b)	9	1	9	2	18
Total					18

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

Dated: September 12, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00-23890 Filed 9-15-00; 8:45 am]

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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; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of August 18, 2000 (65 FR 50541). The document announced an opportunity for public comment on a proposed collection of information, concerning a food safety survey, that has been submitted to the Office of Management and Budget for review and clearance under the Paperwork Reduction Act of 1995. The notice

published with an inadvertent error. This document corrects that error.

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 FR Doc. 00N-21007 appearing on page 50541 in the **Federal Register** of Friday, August 18, 2000, the following correction is made:

On page 50541, in the second column, under the heading "Food Safety Survey (OMB Control Number 0910-0345)—Extension", the phrase "Under section 903(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(b)(2))" is corrected to read "Under section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2))".

Dated: September 12, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00-23885 Filed 9-15-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 91G-0253]

Procter & Gamble Co.; Withdrawal of GRAS Affirmation 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 petition (GRASP 1G0373) proposing to affirm that caprenin, a triglyceride derived from the esterification of glycerol with capric, caprylic, and behenic acids, is generally recognized as safe (GRAS) for use as a confectionery fat in soft candy and confectionery coatings.

FOR FURTHER INFORMATION CONTACT:

Paulette M. Gaynor, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3079.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of August 8, 1991 (56 FR 37712) (correction published September 3, 1991 (56 FR 43648)), FDA announced that a

petition (GRASP 1G0373) had been filed by Procter & Gamble Co., 6300 Center Hill Rd., Cincinnati, OH 45224. This petition proposed that the use of caprenin, a triglyceride derived from the esterification of glycerol with capric, caprylic, and behenic acids, as a confectionery fat in soft candy and confectionery coatings be affirmed as GRAS. Procter & Gamble Co. has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: August 30, 2000.

Alan M. Rulis,

*Director, Office of Premarket Approval,
Center for Food Safety and Applied Nutrition.*
[FR Doc. 00-23883 Filed 9-13-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act, (Public Law 92-463), announcement is made of the following National Advisory body scheduled to meet during the month of October 2000.

Name: Advisory Committee on Interdisciplinary, Community-Based Linkages.

Date and Time: October 10, 2000, 10 a.m.–5 p.m.; October 11, 2000, 10 a.m.–4 p.m.

Place: The Doubletree Hotel Park Terrace on Embassy Row, 1515 Rhode Island Avenue, NW., Washington, DC 20005.

The meeting is open to the public.

The full Committee will meet beginning October 10 and adjourn on October 11, during the hours cited above. Agenda items will include, but not be limited to: Review and approval of the August 13–14, 2000, Committee meeting minutes; plenary discussion of programmatic challenges facing the seven federal programs to be reviewed by the Committee: Geriatrics Education and Training Programs, Allied Health Programs, the Quentin N. Burdick program for Rural Interdisciplinary Training, Area Health Education Centers, Health Education and Training Centers, Chiropractic, and Podiatric Medicine; introduction of Division of Interdisciplinary and Community-Based Program (DICP) staff supporting Committee activities and federal program management of the programs listed above; Committee team break-out meetings followed by plenary session outcomes reporting; discussion and planning of the Committee report due to the Secretary of Health and Human Services, the Committee on Health, Education, Labor and Pensions (formerly the Committee on Labor and Human Resources) of the Senate, and the Committee on Commerce of the House of Representatives by November 2001; and

scheduling of the next Committee meeting, which shall include but not be limited to: the meeting date and location and discussion of topics to be addressed during the meeting.

Public comment will be permitted before lunch and at the end of the Committee meeting on October 11, 2000. Oral presentations will be limited to five minutes per public speaker. Persons interested in providing an oral presentation should submit a written request, with a copy of their presentation to: Mr. Leo Wermers, Principal Staff Liaison, Division of Interdisciplinary, Community-Based Programs, Bureau of Health Professions, Health Resources and Services Administration, Room 9-105, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443-1648 or (301) 443-7121.

Requests should contain the name, address, telephone number, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The Division of Interdisciplinary, Community-Based Programs will notify each presenter by mail or telephone of their assigned presentation time.

Persons who do not file an advance request for a presentation, but wish to make an oral statement may register to do so at the Doubletree Hotel Park Terrace on October 10, 2000. These persons will be allocated time as the Committee meeting agenda permits.

Anyone requiring information regarding the Committee should contact Mr. Wermers, Division of Interdisciplinary, Community-Based Programs, Bureau of Health Professions, Health Resources and Services Administration, Room 9-105, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443-1648 or (301) 443-7121.

Proposed agenda items are subject to change as priorities dictate.

Dated: September 8, 2000.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 00-23818 Filed 9-15-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request: Evaluation of a Public Education Campaign on Drinking During Pregnancy

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, regarding the opportunity for public comment on proposed data collection projects, the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects

submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: Evaluation of a Public Education Campaign on Drinking During Pregnancy. *Type of Information Collection Request:* New Collection. *Need and Use of Information Collection:* The evaluation is being conducted to determine whether the public education campaign on alcohol consumption during pregnancy raises awareness and attentiveness to the problems of drinking during pregnancy among the target audience of African American women ages 21–29 residing in Washington, DC. The public education campaign, funded by NIAAA, is in response to a need for increased awareness among African American women of childbearing age about the consequences of drinking during pregnancy, the most severe of which is Fetal Alcohol Syndrome (FAS). The two-year campaign will be launched during the spring of 2001, and will serve as a pilot program for possible replication in other communities across the country. The information from the evaluation of the public information campaign is to be used by NIAAA to inform policy and practice related to public education efforts targeted toward preventing drinking during pregnancy. The collection of information will take place at two points (pretest and posttest): (1) In the spring, 2001, prior to commencement of the public education campaign, to gather baseline data on knowledge of the effects of drinking during pregnancy; and (2) in the winter, 2003, immediately following the conclusion of the public education campaign, to determine whether the message to the target audience had its intended effect. The data collected will be analyzed to: (1) increase understanding about the extent of African American women's knowledge of the risks of drinking during pregnancy; (2) evaluate whether a public education campaign targeted towards African American women is effective in increasing awareness; and (3) assess the campaign's strengths and weaknesses in order to provide guidance to other similar public education campaigns.

The public education campaign and evaluation are new efforts that will continue for approximately two years. *Frequency of Response:* Once per respondent. Potential respondents will be screened to avoid including individuals in both the pre- and post-test intervals as well as including individuals multiple times in a single test interval. *Affected Public:*