

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

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 <sup>2</sup>
314.70	2	1	1	20	40 <sup>3</sup>
Total					1,160

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

<sup>2</sup> Reporting burden for manufacturers of nonsterile products.

<sup>3</sup> 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 BURDEN<sup>1</sup>

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

<sup>1</sup> 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.*

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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.*

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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