Dated: September 12, 2000.

Nancy Cheal,

Acting Associate Director for Policy Planning, and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 00–23859 Filed 9–15–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1489]

Agency Information Collection Activities; Proposed Collection; Comment Request; Sterility Requirements for Aqueous-Based Drug Products for Oral Inhalation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting and recordkeeping requirements associated with sterility requirements for aqueous-based drug products for oral inhalation.

DATES: Submit written or electronic comments on the collection of information by November 17, 2000.

ADDRESSES: Submit electronic comments on the collection of information via the Internet at http://www.accessdata.fda.gov/scripts/oc/edockethome.cfm. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, 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.

Sterility Requirements for Aqueous-Based Drug Products for Oral Inhalation (formerly known and approved under Sterility Requirements for Inhalation Solution Products) (OMB Control No. 0910–0353)

Sections 314.70(b) and 314.97 (21 CFR 314.70(b) and 314.97) require that all aqueous-based drug products for oral inhalation, including those currently approved, be manufactured sterile. Respondents will be required to submit a supplemental application under § 314.70(b) or § 314.97, describing their new manufacturing process for achieving sterility of their aqueous-based drug products for oral inhalation. FDA needs this information to determine compliance with this new regulation and will use information collected to make decisions on approval of supplemental applications.

Based on new information collected by its contractor, ERG, FDA has revised its estimate of the number of respondents in the original proposal for reporting and recordkeeping burden. Because the respondents have changed, the estimate of the total hours have changed. In the proposed rule it was estimated that there were 5 manufacturers, while the final rule estimates there are 8 manufacturers with 11 nonsterile products based on new data collected by ERG. However, four of the manufacturers are projected to cease manufacturing, leaving four companies manufacturing seven products. These companies are projected to cease manufacturing because they may lack the in-house technical capability to convert their operations or might find the prospective investments in sterile production technologies to be unattractive. Because each nonsterile product will require an annual report (21 CFR 314.81(b)(2)(iv)), the number of annual responses for nonsterile products has increased to seven. Based on a review of FDA's past experience with applicants submitting supplemental applications under § 314.97, we estimate 160 hours to prepare a supplemental application. Therefore, due to the increased estimate of respondents, the total hours for the annual reporting burden for manufacturers of nonsterile products has increased from 800 hours in the proposed rule to 1,120 hours in the final rule. The agency's review of the estimated reporting burden for manufacturers of sterile products in the proposed rule and its experience with the annual reporting burden for manufacturers of sterile products supported the estimate provided in the proposed rule. Therefore, the estimated reporting burden for manufacturers of sterile products is the same as in the proposed rule.

Respondents to this information collection are businesses engaged in the manufacture of aqueous-based drug products for oral inhalation.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

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 BURDEN[1]

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]

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; 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]

BILLING CODE 4160–01–F

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