TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section	Number of Respondents	Number fo Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
MARKETING EXCLUSIVITY INFORMATION 314.50(j) 314.54(a)(1)(vii) 314.70(f)	92	2.7	250	2	500
NOTIFICATION OF DATE OF COMMERCIAL MARKETING; ENTRY OF THE ORDER OR JUDGEMENT; FILING OF LEGAL ACTION 314.107(c)(4),(e)(2)(iv),(f)(2), and (f)(3)	34	2	71	1	71
TOTAL					3,083

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

Dated: December 26, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–45 Filed 1–2–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1505]

Agency Information Collection Activities; Announcement of OMB Approval; Guidance for Industry on How to Use E–Mail to Submit a Notice of Intent to Slaughter for Human Food Purposes

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Guidance for Industry on How to Use E–Mail to Submit a Notice of Intent to Slaughter for Human Food Purposes'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 21, 2000 (65 FR 57192), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0450. The approval expires on November 30, 2003. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: December 26, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–46 Filed 1–2–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1489]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Sterility Requirements for Aqueous-Based Drug Products for Oral Inhalation (Formerly Known and Approved Under Sterility Requirements for Inhalation Solution Products) (OMB Control Number 0910–0353)

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 February 2, 2001.

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: 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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Sterility Requirements for Aqueous-Based Drug Products for Oral Inhalation (Formerly Known and Approved Under Sterility Requirements for Inhalation Solution Products) (OMB Control Number 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	2	20	40[3]
Total					1,160

[1] There are no capital costs or operating and maintenance 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

21 CFR Section	No. of Record-keepers	Annual Frequency per Record-keepers	Total Annual Records	Hours per Record	Total Hours
211.113(b)	9	1	9	2	18
Total					18

In the **Federal Register** of September 18, 2000 (65 FR 56314), the agency requested comments on the proposed collections of information. No comments were received.

Dated: December 26, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–48 Filed 1–2–01; 8:45 am]

BILLING CODE: 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99F–2081]

Troy Corp.; Filing of Food Additive Petition; Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is amending the filing notice for a food additive petition filed by Troy Corp. to indicate that the petitioner has proposed that the food additive regulations be amended to provide for the safe use of butanedioic acid, sulfo-1,4-diisodecyl ester, ammonium salt as a surface active agent in adhesives, in pressure-sensitive adhesives, and in paper and paperboard 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 July 2, 1999 (64 FR 36021), FDA announced that a food additive petition (FAP 9B4678) had been filed by Troy Corp., c/o S. L. Graham & Associates, 1801 Peachtree Lane, Bowie, MD 20721. The petition proposed to amend the food additive regulations in § 175.125 *Pressure-sensitive adhesives* (21 CFR 175.125) to provide for the safe use of butanedioic acid, sulfo-1,4-diisodecyl ester, ammonium salt as a surface active agent in pressure sensitive adhesives.

Subsequent to the publication of the filing notice, the petition was amended to include a proposal to further amend the food additive regulations in 21 CFR 175.105 *Adhesives*, 21 CFR 176.170 *Components of paper and paperboard in contact with aqueous and fatty food*, 21 CFR 176.180 *Components of paper and paperboard in contact with dry foods*, and 21 CFR 178.3400 *Emulsifiers and/or surface active agents* to provide for the safe use of butanedioic acid, sulfo-1,4-diisodecyl ester, ammonium salt as a surface active agent in adhesives, and in paper and paperboard intended to contact food.

Therefore, FDA is amending the filing notice of July 2, 1999, to indicate that the petitioner requests that the food