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]

BILLING CODE 4160–01–F

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]

BILLING CODE 4160–01–F

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