

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

DMB

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[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.

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**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 *[insert date 30 days after date of publication in the Federal Register]*.

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

<sup>1</sup> There are no capital costs or operating and maintenance 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

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. 00-<sup>1</sup>????? Filed ??-??-00<sup>1</sup>; 8:45 am]

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