

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB

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[Docket No. 00N-1303]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Agreement for Shipment of Devices for Sterilization

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

Agreement for Shipment of Devices for Sterilization—21 CFR 801.150(e) (OMB Control No. 0910-0131)—Extension

Under sections 501(c) and 502(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351(c) and 352(a)), nonsterile devices that are labeled as sterile but are in interstate transit to a facility to be sterilized are adulterated and misbranded. FDA regulations in § 801.150(e) (21 CFR 801.150(e)) establish a control mechanism by which firms may manufacture and label medical devices as sterile at one establishment and ship the devices in interstate commerce for sterilization at another establishment, a practice that facilitates the processing of devices and is economically necessary for some firms. Under § 801.150(e), manufacturers and sterilizers may sign an agreement containing the following: (1) Instructions for maintaining accountability of the number of units in each shipment; (2) acknowledgment that the devices are nonsterile, being shipped for further processing; and (3) specifications for sterilization processing.

This agreement allows the manufacturer to ship misbranded products to be sterilized without initiating regulatory action and provides FDA with a means to protect consumers from use of nonsterile products. During routine plant inspections, FDA normally reviews agreements that must be kept for 2 years after final shipment or delivery of devices. The respondents to this collection of information are device manufacturers and contract sterilizers.

In the **Federal Register** of June 12, 2000 (65 FR 36816), the agency requested comments on the proposed collection of information. No significant comments were received.

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

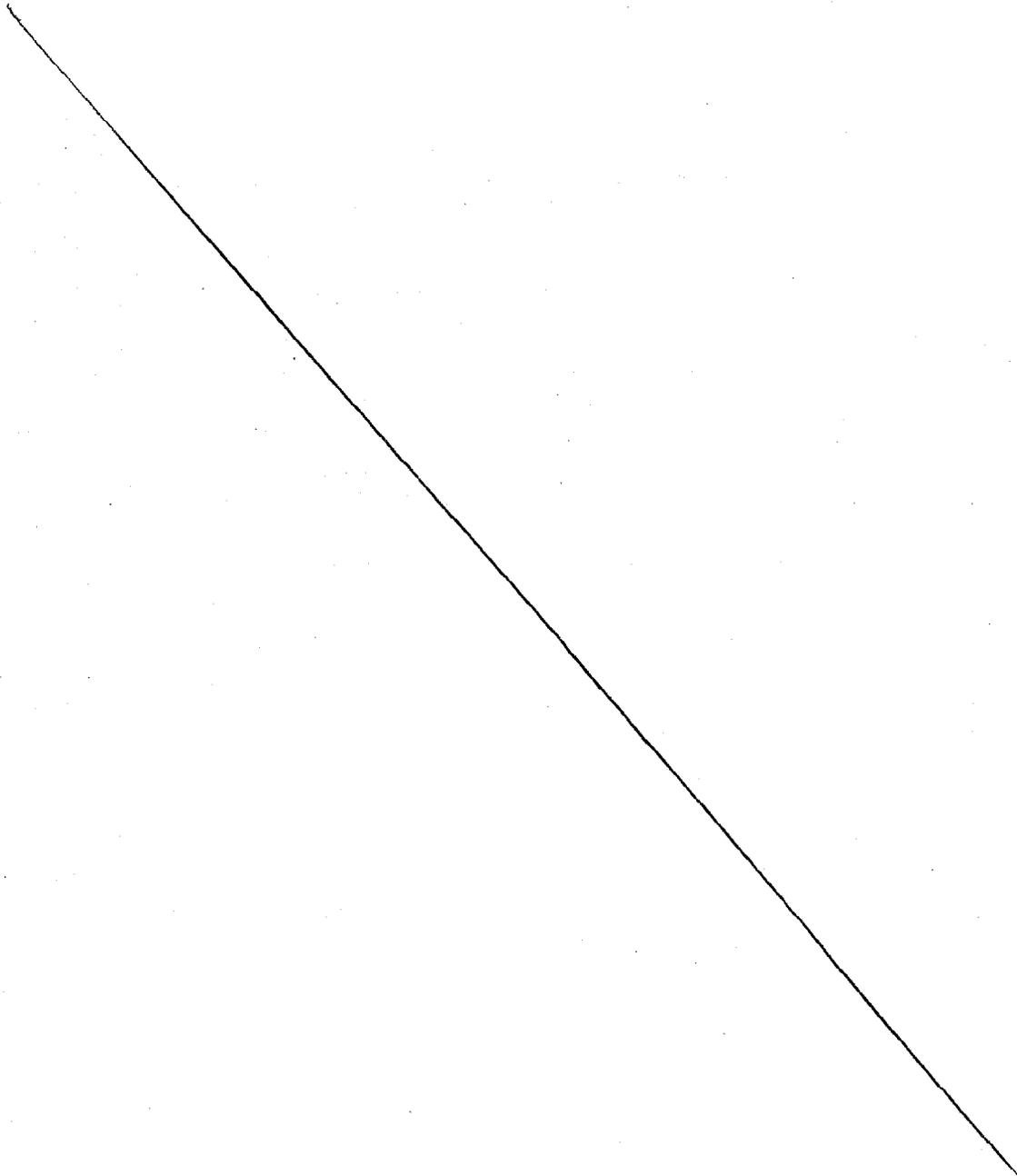
TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
801.150(e)	80	20	1,800	4	7,200
Total					7,200

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

FDA's estimate of the burden is based on actual data obtained from industry during the past 3 years where there are approximately 90 firms subject to this requirement.

No burden has been estimated for the recordkeeping requirement in § 801.150(a)(2) because these records are maintained as a usual and customary part of normal business activities. Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection



of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities.

Dated: September 7, 2000
September 7, 2000.

William Hubbard

William K. Hubbard,
Senior Associate
Commissioner for Policy,
Planning, and Legislation.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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Sydney N. Reese