

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0456]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prevention of Medical Gas Mixups at Health Care Facilities; Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: The Office of Management and Budget (OMB) is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (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.

Prevention of Medical Gas Mixups at Health Care Facilities Background

FDA has received four reports of medical gas mixups occurring during the past 5 years. These reports were received from hospitals and nursing homes and involved 7 deaths and 15 injuries to patients who were thought to be receiving medical grade oxygen, but who were actually receiving a different gas (e.g., nitrogen, argon) that had been mistakenly connected to the facility's oxygen supply system. In 2001, FDA published guidance making recommendations to help hospitals, nursing homes, and other health care facilities avoid the tragedies that result from medical gas mixups and alerting these facilities to the hazards. This survey is intended to assess the degree of facilities' compliance with safety measures to prevent mixups, to determine if further steps are warranted to ensure the safety of patients.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Part	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
210 and 211	285	1	285	.25	71.25
Total	285	1	285	.25	71.25

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

In the **Federal Register** of October 10, 2003 (68 FR 58691), FDA published a 60-day notice requesting public comment on the information collection provisions. The agency received two comments. One comment had specific questions regarding the requirements to register firms exporting foods from Korea.

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The responder of the second comment feels the agency is gathering facts with the intent of developing and implementing future guidance that would be enforced on manufacturers, fillers, and transfillers of medical gases. This comment also requests the agency meet with the medical gases industry prior to issuing any guidance.

The intent of this survey is stated previously and is not applicable to the medical gases industry.

The agency does however, agree with the statement addressed in the second comment regarding the initial contact FDA makes with the 285 facilities would be more effective and save valuable resources if made via telephone. This call could determine whether the health care facility is one of those covered by this assignment and our April 6, 2001, FDA Public Health Advisory—Guidance for Hospitals, Nursing Homes, and other Health Care Facilities.

Dated: June 16, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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