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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Display Date 10.9.03
Publication Date 10.10.03
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Food and Drug Administration

[Docket No. 2003N-0456]

Agency Information Collection Activities; Proposed Collection; Comment Request; Prevention of Medical Gas Mixups at Health Care Facilities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on measures taken by certain Health Care medical facilities that use medical oxygen to prevent mixups with other gases.

DATES: Submit written or electronic comments on the collection of information by *[insert date 60 days after date of publication in the **Federal Register**]*.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Oxygen Manufacturers and Fillers—21 CFR Parts 210 and 211

The Food and Drug Administration (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 Section	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 of information.

Dated: OCT 6 2003
October 6, 2003.

Jeffrey Shuren

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

BILLING CODE 4160-01-S

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Colin Lendley