

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0146]

DDM

Display Date 7-30-08
Publication Date 7-31-08
Certifier A. Corbin

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Requirements for Collection of Data Relating to the Prevention of Medical Gas Mix-ups 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: 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: FDA Desk Officer, FAX: 202-395-6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910-0548. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3792.

0C08177
FDA-2008-N-0146

N

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.

Requirements for Collection of Data Relating to the Prevention of Medical Gas Mix-ups at Health Care Facilities-Survey—(OMB Control Number 0910-0548)—Extension

On March 7, 2008 (73 FR 12452) and July 1, 2008 (73 FR 37465) respectively, FDA published a 60-day and 30-day notice stating that it had received 4 reports of medical gas mix-ups occurring during the past 9 years which 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. These reported incidents actually occurred between 1998 and 2000 which, at the time, prompted the FDA in 2001 to publish guidance making recommendations to help hospitals, nursing homes, and other health care facilities avoid the tragedies that result from medical gas mix-ups and alerting these facilities to the hazards. This survey is intended to assess the degree of facilities' compliance with safety measures to prevent mix-ups, to determine if further steps are warranted to ensure the safety of patients.

In the **Federal Register** of March 7, 2008 (73 FR 12452), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING 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: 7/25/08

July 25, 2008.

Jeffrey Shuren

Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

BILLING CODE 4160-01-S

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

[Signature]
