SUPPORTING STATEMENT

Requirements for Collection of Data Relating to the Prevention of Medical Gas Mix-ups at Health Care Facilities Survey

OMB Control Number 0910-0548

A. Justification

1. Circumstances of Information Collection

The Food and Drug Administration (FDA) plans to conduct a survey to determine the rate of compliance with its recommendations pertaining to Health Care Facilities and to determine the success rate at preventing medical gas mix-ups from occurring. FDA received reports of medical gas mix-ups occurring during the past 9 years. These reports involved hospitals and nursing home facilities and involved 7 deaths and 15 injuries to patients who were thought to be receiving medical grade oxygen, but instead were actually receiving a different gas that had been mistakenly connected to the facility's oxygen supply system.

2. Purpose and Use of Information

To assess the effectiveness of implementing FDA's recommendations on the prevention of medical gas mix-ups at hospitals, nursing homes, and health care facilities. Implementing all of the recommendations will result in increased protection of the public health by assuring that the employees of hospitals, nursing homes and health care facilities receive adequate training in understanding the hazardous associated with handling medical gases. This should provide a higher degree of certainty that only

medical grade oxygen is connected to an oxygen supply system.

3. Use of Improved Information Technology

Even though advanced technologies for the gathering and reporting of data possibly do exist, investigators collect this information during their usual and customary investigators workday.

4. Efforts to Identify Duplication

This assignment is unique in that there are no regulatory requirements for health care facilities. However, hospitals, nursing homes, and health care facilities were requested to voluntarily implement our recommendations that will greatly enhance the degree of safety associated with connecting medical grade oxygen to their oxygen supply system.

5. Involvement of Small Entities

FDA investigators will visit a representative number of health care facilities and speak to the managers responsible for the handling of medical gases. The managers will be asked to provide answers to several assignment questions. So under the Regulatory Flexibility Act, there will only minimal impact on small entities.

6. Consequences If Information Collected Less Frequently

This is a one-time survey.

7. Consistency with the Guidelines in 5 CFR 1320.5(d)(2)

There is no inconsistency resulting from this survey.

8. Consultation Outside the Agency

As required under section 3506 (c)(2)(B) of the Paperwork Reduction Act, FDA provided an opportunity for public comment on January 3, 2006 (71 FR 122). No comments were received on the information collection estimates.

9. Remuneration of Respondents

FDA has not provided and has no intention to provide any payment or gift to respondents under this guidance.

10. Assurance of Confidentiality

Confidentiality of information is protected under 21 CFR 314.430, 21 CFR 601, and 21 CFR part 20.

11. Questions of a Sensitive Nature

There are no questions of a sensitive nature.

12. Estimates of Annualized Hour Burden

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
210/211	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.

13. Estimates of Annualized Cost Burden to Respondents

FDA has estimated that the cost to health care facilities would be minimal, and would only involve the time it takes for management to provide a response to each question.

14. Estimates of Annualized Cost Burden to the Government

The investigators will include a visit to the assigned health care facilities on their normal inspectional coverage of drug firms. The Agency estimates that it will take 1 hour total to cover the assignment.

15. Changes In Burden

There is no change in the burden.

16. Time Schedule, Publication, and Analysis Plans

There are no publications.

17. Displaying of OMB Expiration Date

The agency is not seeking to display the expiration date for OMB approval of the information collection.

18. Exception to the Certification Statement - Item 19

There are no exceptions to the certification statement identified in Item 19, "Certification for Paperwork Reduction Act Submission," of OMB Form 83-I.