FDA Recall Regulations
Docket No. 2004N-0442
OMB No. 0910-0249
Supporting Statement

A. Justification

1. **Circumstances Necessitating Information Collection**

Section 701 of the Federal Food, Drug, and Cosmetic Act (Attachment A), and 21 CFR Part 7, Subpart C (Attachment B), set forth the recall regulations (guidelines) and provide guidance to manufacturers on recall responsibilities. The guidelines apply to all regulated products (i.e., food, including animal feed; drugs, including animal drugs; medical devices, including in vitro diagnostic products; cosmetics; and biological products intended for human use).

The Food and Drug Administration (FDA) is requesting approval from the Office of Management and Budget (OMB) for the information collection requirements contained in:

21 CFR 7.42 - Recall Strategy - Reporting

Requests firms to develop a recall strategy including provisions for public warnings and effectiveness checks.

21 CFR 7.46 - Firm Initiated Recall - Reporting

Requests firms that voluntarily remove or correct foods and drugs (animal or human), cosmetics, medical devices and biologicals to immediately notify the appropriate FDA district office of such actions. The firm is to provide complete details of the recall reason, risk evaluation, quantity produced, distribution information, firms' recall strategy and a contact official.

21 CFR 7.49 - Recall Communications - Reporting

Requires firms to notify their direct accounts of the recall and to provide recipients with a ready means of reporting to the recalling firm.

21 CFR 7.53 - Recall Status Reports - Reporting

Requests that recalling firms provide periodic status reports so the FDA can access the progress of the recall.

21 CFR 7.55(b) - Termination of a Recall - Reporting

Provides an opportunity for a firm to request in writing that FDA terminate the recall.

2. How, By Whom, Purpose of Collection

The agency recognizes that situations may arise involving health risks presented by unsafe products. The recall provisions of 21 CFR Part 7, Subpart C provide the information necessary for the FDA to monitor recalls and assess the adequacy of a firm's efforts in a recall. It also permits FDA to evaluate whether a recall has been completed in a manner, which assures that unreasonable risk of substantial harm to the public health has been eliminated.

3. Consideration Given to Information Technology

The FDA is continuously seeking ways to reduce the reporting burden through advances in information technology.

4. Identification of Information

The recall regulation imposes a burden that is not duplicative of any comparable requirement imposed by government or industry, to FDA's knowledge. Similar information is not available to FDA.

5. Small Businesses

The requirements will not fall disproportionately on small business. It is not possible to provide an exemption for small business or to reduce the requirements for small business without seriously compromising the public health. However, FDA does assist small business through the Office of Small Manufacturers Assistance.

6. Less Frequent Information Collection

The impact of not collecting the information or requiring the reports and notification in those instances where FDA has determined that recall should be conducted could seriously compromise the public health.

7. Special Information Collection Circumstances

The information collection requirements in this request are inconsistent with that outlined in 5 CFR 1320.6. The reports are obtained more often than quarterly. Section 21 CFR 7.53(a), requests the recalling firm to submit status reports to the FDA, determined by the urgency of the recall, between 2 and 4-week intervals.

8. Outside Consultation

In accordance with 5 CFR 1320.8(d), on October 12, 2004 (Volume 69 No. Page 60630,) a 60-day notice for public comment (Attachment) was published in the Federal Register. no comment(s) were received from the public.

Discuss Comments and respond.

9. Payment or Gift

No payment or gift was provided.

10. Confidentiality Provisions

No sensitive information is sought under this guideline. Some confidential commercial information may be reported to FDA but FDA's public information regulations (21 CFR Part 20) will govern the release of data.

11. Privacy

Questions of a sensitive nature are not applicable to this information collection.

12. Burden of Information Collection

Recognizing that there may be a vast difference in the information collection and reporting time involved in different recalls of FDA's regulated products, FDA estimates on average the burden of collection for recall information to be 210,875 hours. Estimated annual burden hours for manufacturers, processors, and distributors to comply with the voluntary reporting requirements of FDA's recall regulations.

Estimated Annual Reporting Burden

21 CFR	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Responses	Burden Hours (rounded to nearest one
7.42	2375	1	2375	15	35625
7.46 & 7.49	2375	1	2375	20	47500
7.53	2375	4	9500	10	95000
7.55(b)	2375	1	2375	10	23750
Total					201,875

13. Cost to Respondents

The FDA has no information which would allow it to make any meaningful estimate of the cost to FDA regulated Industry to conduct recalls. Variables in the type of products, the quantity and level of distribution and the various circumstances of recall notifications could cause a recall to vary in cost from less that $1,000.00 to more than $1,000,000.00

14. Costs to Federal Government

During FY 2003, FDA classified 2375 industry actions as recalls. Each of the 2375 situations underwent a review process to determine if it met the recall definition, what hazard to health existed, to what level the recall should extend, what classification was appropriate, and the number of FDA audit checks necessary to assure consumer protection. The total costs for reviewing, classifying, auditing and monitoring the 2375 actions in FY 2003 were approximately $8,119,200.

The government's cost increased from $5,249,680 in previous years to $8,119,200 due to the increase in the number of audit checks accomplished by investigators.

The 2375 recalls, in FY 2003, resulted in approximately 41,562 hours spent making audit checks, etc. The projected investigator man years (MY) is 940 resulting in a total of 44.2 operational FTEs. There are 1.8 support FTEs for each operational FTE for a total of 79.6 supported FTEs and the current annual salary of $102,000 per FTE or (41,562 hours divided by 940 (MY) = 44.2 operational FTEs x 1.8 support FTEs = 79.6 supported FTEs x $ 102,000/FTE =$8,119,200).

15. Reason for Change

The burden for this submission has increased from 157,675 hours to 201,875 hours annually due to an increase in the number of recalls.

16. Statistical Reporting

The reporting requirements contained in this proposal are not statistical in nature and the records are not published for statistical use.

17. Display of OMB Approval Date

We are not seeking approval to exempt display of the OMB approval date on any documents that are associated with this information collection.

18. Exceptions to "Certification for Paperwork Reduction Act Submissions"

There are not exceptions to "Certification for Paperwork Reduction Act Submissions" for this collection of information.

I certify that time recorded is accurate:

Employee Signature: ____