DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0442]

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Certifier R. VEDESMA

Agency Information Collection Activities; Proposed Collection; Comment Request; Recall Regulations (Guidelines)

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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on FDA's recall regulations (guidelines) and provides guidance to manufacturers on recall responsibilities.

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 to 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.

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FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

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, including each proposed extension of an existing 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.

FDA Recall Regulations—21 CFR Part 7 (OMB Control Number 0910–0249)

Section 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371) and part 7 (21 CFR part 7), subpart C sets forth the recall regulations (guidelines) and provides guidance to manufacturers on recall responsibilities. The guidelines apply to all FDA-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). These responsibilities include development of a recall strategy that requires time by the firm to determine the actions or procedures required to manage the recall (§ 7.42); providing FDA with complete details of the recall including reason(s) for the removal or correction, risk evaluation, quantity produced, distribution information, firm's recall strategy, a copy of any recall communication(s), and a contact official (§ 7.46); notifying direct accounts of the recall, providing guidance regarding further distribution, giving instructions as to what to do with the product, providing recipients with a ready means of reporting to the recalling firm (§ 7.49); submitting periodic status reports so that FDA may assess the progress of the recall. Status report information may be determined by, among other things evaluation return reply cards, effectiveness checks and product returns (§ 7.53); and providing the opportunity for a firm to request in writing that FDA terminate the recall (§ 7.55).

A search of the FDA database was performed to determine the number of recalls that took place during fiscal year 2003. The resulting number of recalls from this database search (2,375) is used in estimating the current annual reporting burden for this report. FDA estimates the total annual

industry burden to collect and provide the above information to 201,875 burden hours.

The following is a summary of the estimated annual burden hours for recalling firms (manufacturers, processors, and distributors) to comply with the voluntary reporting requirements of FDA's recall regulations.

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 as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Recall Strategy (§ 7.42)	2,375	1	2,375	15	35,625
Firm Initiated Recall & Public Warnings Recall Communications (§§ 7.46 and 7.49)	2,375	1	2,375	20	47,500
Recall Status Reports and Followup (§ 7.53)	2,375	4	9,500	10	95,000
Termination of a Recall (§ 7.55(b))	2,375	1	2,375	10	23,750
Total					201,875

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

The annual reporting burdens are explained as follows:

Recall Strategy

Requests firms to develop a recall strategy including provision for public warnings and effectiveness checks. Under this portion of the collection of information, the agency estimates it will receive 2,375 responses annually.

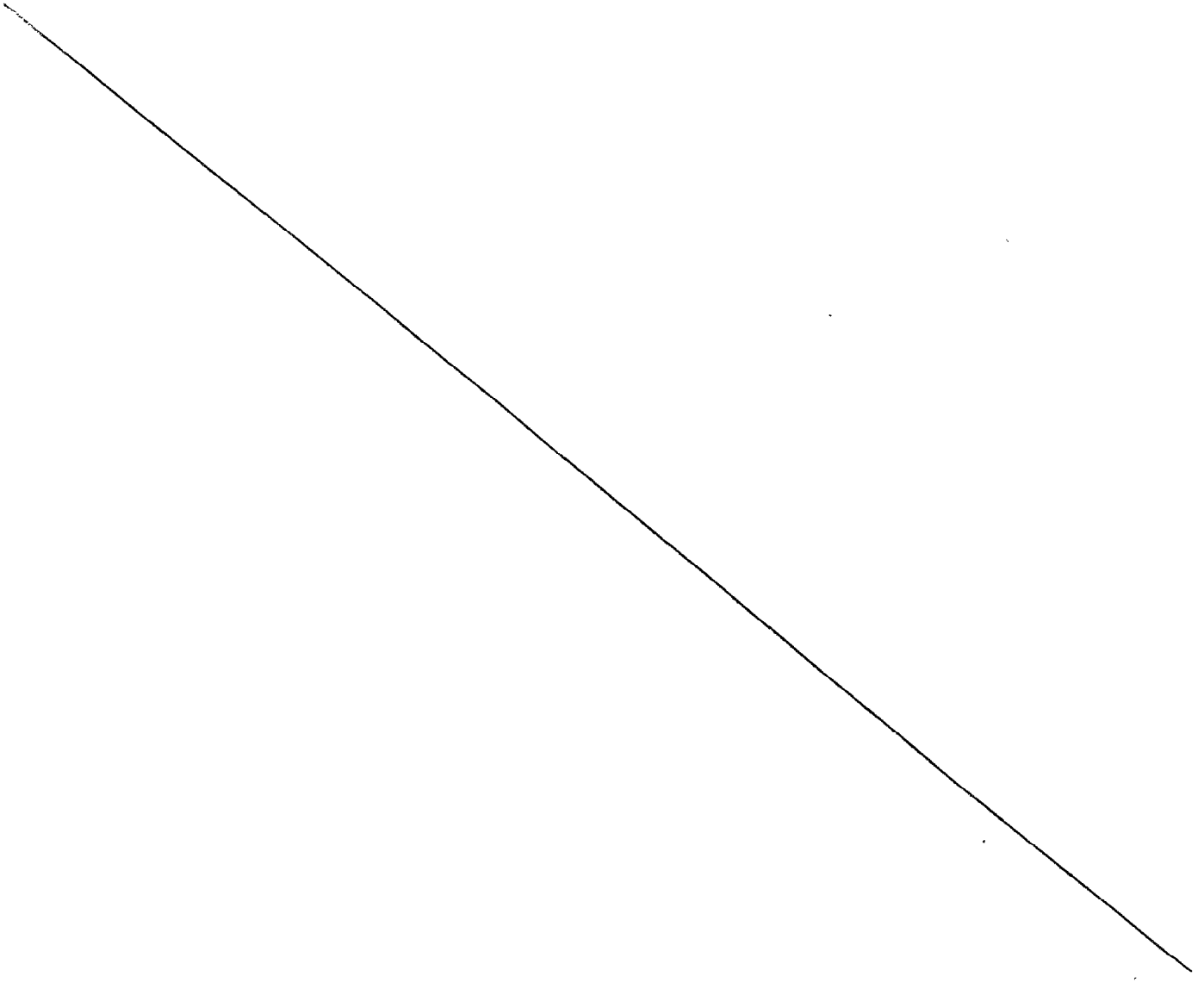
Firm Initiated Recall and Recall Communications

Requests firms that voluntarily remove or correct voluntarily foods and drugs (human or animal), cosmetics, medical devices, and biologicals to immediately notify immediately 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 as well as requires firms to notify their direct accounts of the recall and to provide recipients with a ready means of reporting to the recalling firm. Under these portions of the collection of information, the agency estimates it will receive 2,375 responses annually for each.

Recall Status Reports

Requests that recalling firms provide periodic status reports so FDA can ascertain the progress of the recall. This collection of information will generate approximately 9,500 responses annually.



Termination of a Recall

Provides the firm an opportunity to request in writing that FDA end the recall. The agency estimates it will receive 2,375 responses annually.

Dated: 10/4/04
October 4, 2004.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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