information collection and has assigned OMB control number 0910–0052. The approval expires on March 31, 2009. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: April 3, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–5146 Filed 4–7–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0190]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Export Certificates for Food and Drug Administration-Regulated Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Export Certificates for FDA-Regulated Products'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 25, 2006 (71 FR 4147), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0498. The approval expires on March 31, 2009. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: April 3, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–5148 Filed 4–7–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0389]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Reprocessed Single-Use Device Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Reprocessed Single-Use Device Labeling'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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: In the **Federal Register** of December 15, 2005 (70 FR 74324), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0577. The approval expires on January 31, 2009. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: April 3, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–5150 Filed 4–7–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0343]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Requesting an Extension to Use Existing Label Stock After the Trans Fat Labeling Effective Date of January 1, 2006

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 May 10, 2006.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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.

Guidance for Requesting an Extension to Use Existing Label Stock After the Trans Fat Labeling Effective Date of January 1, 2006—(OMB Control Number 0910–0571)—Extension

FDA issued a final rule (the *trans* fat final rule) on July 11, 2003, (68 FR 41434) to require food labels to bear the gram (g) amount of *trans fat* without a percent Daily Value (% DV) directly under the saturated fat line on the Nutrition Facts panel (*http://www.cfsan.fda.gov/~acrobat/fr03711a.pdf).* The *trans* fat final rule affects almost all manufacturers of packaged, labeled food sold in the United States. FDA believes that most businesses, including small

businesses, should not have difficulty meeting the January 1, 2006, effective date of the *trans* fat final rule. However, under certain circumstances some businesses may want to request that the agency consider an extension of time to use current labels that are not in compliance with the *trans* fat final rule. The agency believes that it would be appropriate to consider, on a case-by-case basis, whether to exercise enforcement discretion on the January 1, 2006, effective date for *trans fat* labeling for some businesses that can make an appropriate showing. Thus, in the **Federal Register** of December 14, 2005 (70 FR 74020), FDA announced the availability of a guidance document for industry and FDA entitled ''Requesting an Extension to Use Existing Label Stock After the *Trans* Fat Labeling Effective Date of January 1, 2006.'' That document provides guidance to FDA and the food industry about when and how businesses may request the agency to consider enforcement discretion for the use of some or all existing label stock, that does not declare *trans* fat labeling in compliance with the final rule, on products introduced into interstate commerce on or after the January 1, 2006, effective date.

The agency intends to consider the following factors in any request from a firm for the agency's exercise of enforcement discretion:

- Whether products contain 0.5 g or less *trans* fat;
- The explanation of why the request is being made;
- The number of existing labels that the firm is requesting to use;
- The dollar amount associated with the number of existing labels to be used; and
- The estimate of the amount of time needed, not exceeding 12 months, to exhaust the number of existing labels the firm is requesting to use.

Firms may submit their requests in writing to FDA's Center for Food Safety and Applied Nutrition. Firms are encouraged to keep this letter of request for their records and should make a copy available for inspection to any FDA officer or employee who requests it. FDA intends to use the information in the letter to make decisions about whether a firm's product is subject to FDA's enforcement discretion for the *trans* fat labeling requirements. FDA expects that small businesses and very small businesses are the firms most likely to take advantage of this opportunity to submit a request for an extension to the *trans* fat labeling deadline. FDA estimates a 2-year time period during which these requests will be made following the issuance of this guidance. Beyond 2 years time, FDA expects businesses to fully comply with the *trans* fat labeling final rule, as it is unlikely that there will still be old labeling stock remaining.

In previous **Federal Register** notices regarding this collection of information (70 FR 52108 and 70 FR 70621), the estimated number of requests was lower than the actual number of requests received by the agency in response to the guidance. Thus, we have increased the estimated number of requests based on FDA's recent experience. In the **Federal Register** of November 22, 2005 (70 FR 70621), FDA published a 60-day notice requesting public comment on the information collection provisions. We received four comments; however, none were related to the information collection.

FDA estimates that it will take one employee approximately 4 hours to put together a request to FDA and approximately 1 hour for a supervisor to look over the request before submitting it to the agency. Thus, each firm submitting a compliance extension request will need 5 hours of employee time to complete the request. Given that 600 businesses are expected to submit written requests in year one, the total burden hours for year one is 3,000 hours.

In year two, FDA expects about one-half as many businesses to request a labeling compliance extension. So, for year two, 300 businesses are expected to file a request for an extension to the labeling compliance date. Again, assuming that it will take 5 hours to complete each request, the total burden hours for year two will be 1,500 hours.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Written requests to FDA in year one	600	1	600	5	3,000
Written requests to FDA in year two	300	1	300	5	1,500
One time burden hours for years one and two					4,500

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

Dated: April 3, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–5199 Filed 4–7–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1998D–1218]

Guidance for Industry: Gamma Irradiation of Blood and Blood Components: A Pilot Program for Licensing; Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of a guidance that was issued on March 15, 2000.

DATES: April 10, 2006.

FOR FURTHER INFORMATION CONTACT: Pamela Pope, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of March 15, 2000 (65 FR 13982), FDA announced the availability of a guidance entitled ''Guidance for Industry: Gamma Irradiation of Blood and Blood Components: A Pilot Program for Licensing.'' This guidance described a