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

pilot program in which biologics manufacturers could self-certify conformance to licensing criteria prescribed by FDA. This action was intended to reduce unnecessary burdens for industry without diminishing public health protection.

The guidance is being withdrawn because FDA has determined that there is a lack of industry interest in pursuing the pilot licensing program outlined in the guidance.

Dated: March 31, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–5204 Filed 4–7–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0121]

Guidance for Industry and Food and Drug Administration Staff; In Vitro Diagnostic Devices to Detect Influenza A Viruses: Labeling and Regulatory Path; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''In Vitro Diagnostic Devices to Detect Influenza A Viruses: Labeling and Regulatory Path.'' FDA is issuing this guidance to inform industry and agency staff of steps that are needed to ensure the safe and effective use of in vitro diagnostic (IVD) devices intended for use in the detection of influenza A (or A/B) virus directly from human specimens. FDA is taking this action because of recent significant public health concerns associated with emergence of an avian influenza A virus strain as a human pathogen in Southeast Asia. This guidance document describes recommendations for fulfilling labeling requirements applicable to all IVDs intended to generally detect influenza A (or A/B) virus directly from human specimens, and outlines the premarket regulatory path for new or modified devices intended to generally detect influenza A virus, or to detect and differentiate, specific novel influenza A viruses infecting humans. This guidance document is immediately in effect, but it remains subject to comment in accordance with the agency's good guidance practices.

DATES: Submit written or electronic comments on this guidance at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''In Vitro Diagnostic Devices to Detect Influenza A Viruses: Labeling and Regulatory Path'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Sally Hojvat, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–0496.

SUPPLEMENTARY INFORMATION:

I. Background

The spread of the influenza A H5N1 virus within bird species, along with sporadic transmission to humans, has heightened awareness of the potential for a novel influenza A virus to cause a pandemic in humans. Novel influenza A viruses are new or re-emergent human strains of influenza A that cause cases or clusters of human disease, as opposed to those human strains commonly circulating that cause seasonal influenza and to which human populations have residual or limited immunity (either by vaccination or previous infection). All of the influenza A (or A/B) devices cleared by FDA under 21 CFR 866.3330 before February 3, 2006, are designed to generally detect influenza A viruses in human respiratory specimens (e.g., washes, aspirates, and swabs). None of these devices is designed or intended to detect a specific influenza A virus, or to detect and differentiate one specific influenza A virus from another (e.g., H5N1 from H3N2). For devices cleared on the basis of performance characteristics established when only influenza A/H3 and A/H1 viruses were circulating, there is no evidence that the devices would reliably detect novel influenza A viruses from human respiratory samples. Also, these testing devices are not intended to detect and differentiate a specific human-infecting novel influenza A virus. FDA is making this guidance document immediately available because prior public participation is not feasible given the national and global public health threat of pandemic influenza. At this time public health officials are expediting plans to prepare for and respond to this threat. Immediate implementation of this guidance is part of this preparedness effort as it clarifies the role of in vitro diagnostic devices for the detection and/or differentiation of novel influenza A viruses.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on labeling and regulatory path for in vitro diagnostic devices to detect influenza A viruses. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

To receive ''In Vitro Diagnostic Devices to Detect Influenza A Viruses: Labeling and Regulatory Path'' by fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number 1549 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.*