

number and be submitted to the address specified under the caption **ADDRESSES**. All communications received on or before the closing date for comments will be considered, and this rule may be amended or withdrawn in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of this action and determining whether additional rulemaking action is needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this action will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. FAA-2006-24448/Airspace Docket No. 06-AGL-02." The postcard will be date stamped and returned to the commenter.

Agency Findings

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule will not have federalism implications under Executive Order 13132.

Further, the FAA has determined that this regulation is noncontroversial and unlikely to result in adverse or negative comments and only involves an established body of technical regulations that require frequent and routine amendments to keep them operationally current. Therefore, I certify that this regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. Since this rule involves routine matters that will only affect air traffic procedures and air navigation, it

does not warrant preparation of a Regulatory Flexibility Analysis because the anticipated impact is so minimal.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

■ Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follow:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854; 24 FR 9565, 3 CFR, 1959-1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9P, Airspace Designations and Reporting Points, dated September 1, 2006, and effective September 15, 2006 is amended as follows:

* * * * *

Paragraph 6002 Class E airspace designated as surface areas.

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AGL WI E2 Mineral Point, WI [New]

Mineral Point, Iowa County Airport, WI
(Lat. 42°53'13" N., long. 90°14'10" W.)
Mineral Point, NDB
(Lat 42°53'17" N., long. 90°13'35" W.)

That airspace extending upward from the surface within a 7.2-mile radius of the Iowa County Airport and within 2.6 miles each side of the 029° bearing from the Mineral Point NDB extending from the 7.2-mile radius to 7.4 miles northeast of the airport.

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Issued in Fort Worth, Texas, on September 22, 2006.

Walter Tweedy,

Acting Manager, System Support Group, ATO Central Service Area.

[FR Doc. 06-8495 Filed 10-4-06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201, 606, and 610

[Docket No. 2005D-0202]

Guidance for Industry on Bar Code Label Requirements—Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of additional questions and answers that are being incorporated into the final guidance document entitled "Guidance for Industry: Bar Code Label Requirements—Questions and Answers." This final guidance is dated October 2006. The additional questions and answers relate to blood and blood components intended for transfusion and requirements that their container labels bear certain machine-readable information. These requirements were part of the final rule on bar code label requirements for human drugs published on February 26, 2004.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the 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>.

FOR FURTHER INFORMATION CONTACT: For products regulated by the Center for Drug Evaluation and Research: Valerie L. Whipp, Center for Drug Evaluation

and Research (HFD-310), Food and Drug Administration, 11919 Rockville Pike, Rockville, MD 20852, 301-827-8957.

For products regulated by the Center for Biologics Evaluation and Research:

Kathleen E. Swisher, 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:

I. Background

In the **Federal Register** of February 26, 2004 (69 FR 9120), FDA published a final rule (the February 2004 final rule) requiring certain human drug and biological products to have on their labels a linear bar code that contains, at a minimum, the drug's NDC number (21 CFR 201.25). The February 2004 final rule requires also that the container label of blood and blood components intended for transfusion bear encoded information in a machine-readable format that must be approved for use by the Director, Center for Biologics Evaluation and Research (21 CFR 606.121(c)(13)).

In the **Federal Register** of April 27, 2006 (71 FR 24856), FDA announced the availability of a final guidance "Guidance for Industry: Bar Code Label Requirements—Questions and Answers." The purpose of the April 2006 guidance was to respond to questions about how the requirements in the February 2004 final rule applied to specific products or circumstances. The questions and answers in the April 2006 guidance focused on bar codes, not machine-readable information on container labels of blood and blood components, because most of the questions we received at that time focused on bar codes. In the April 2006 guidance, we stated that the guidance may be revised as we receive additional questions.

Following publication of the February 2004 final rule and issuance of the April 2006 guidance, FDA received several additional questions concerning blood and blood components and the use of machine-readable information. The answers to these additional questions were provided in the preamble to the February 2004 final rule. We have updated the April 2006 guidance with this additional information to make the information more accessible and convenient. We consider the changes to the April 2006 guidance to be level 2 changes because they set forth existing practices (21 CFR 10.115(c)(2)).

Therefore, FDA is announcing the availability of additional questions and answers incorporated in the document entitled "Guidance for Industry: Bar Code Label Requirements—Questions and Answers," and we are revising the date of the guidance to October 2006.

The guidance is issued consistent with FDA's good guidance practices regulation (21 CFR 10.115), particularly 21 CFR 10.115(g)(4)(i). The guidance represents the FDA's current thinking on this topic. 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 statutes and regulations.

II. Comments

Interested persons may, at any time, submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**) regarding this guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at <http://www.fda.gov/cber/guidelines.htm>, <http://www.fda.gov/cder/guidance/index.htm>, or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: September 26, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6-16436 Filed 10-4-06; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 300

[TD 9288]

RIN 1545-BF68

User Fees Relating to Enrollment

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains amendments to the regulations relating

to user fees for the special enrollment examination to become an enrolled agent, the application for enrollment of enrolled agents, and the renewal of this enrollment. The charging of user fees is authorized by the Independent Offices Appropriations Act (IOAA) of 1952.

DATES: *Effective Date:* November 6, 2006.

Applicability Date: For date of applicability, see § 300.0(c).

FOR FURTHER INFORMATION CONTACT:

Concerning cost methodology, Eva Williams, (202) 622-6400; concerning the regulations, Matthew Cooper, (202) 622-4940 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

This document amends the regulations relating to user fees for the special enrollment examination to become an enrolled agent, the application for enrollment of enrolled agents, and the renewal of this enrollment. The charging of user fees is authorized by the IOAA of 1952, which is codified at 31 U.S.C. 9701.

The IOAA of 1952 authorizes agencies to prescribe regulations that establish charges for services provided by the agency. The charges must be fair and be based on the costs to the government, the value of the service to the recipient, the public policy or interest served, and other relevant facts. The IOAA of 1952 provides that regulations implementing user fees are subject to policies prescribed by the President, which are currently set forth in OMB Circular A-25, 58 FR 38142 (July 15, 1993) (the OMB Circular).

The OMB Circular encourages user fees for government-provided services that confer benefits on identifiable recipients over and above those benefits received by the general public. Under the OMB Circular, an agency that seeks to impose a user fee for Government-provided services must calculate its full cost of providing those services. In general, a user fee should be set at an amount in order for the agency to recover the cost of providing the special service, unless the Office of Management and Budget grants an exception.

On August 29, 2006, a notice of proposed rulemaking (REG-145154-05) was published in the **Federal Register**. Approximately 40 written comments responding to the proposed regulations were received. A public hearing was held on September 29, 2006, but there were no requests to speak at the hearing. After consideration of the comments, the proposed regulations are adopted by this Treasury decision.