

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.

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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.

Enrolled Agent Program

Section 330 of Title 31 of the United States Code authorizes the Secretary of the Treasury to regulate practice before the Treasury Department. Pursuant to section 330 of Title 31, the Secretary has published regulations governing practice before the IRS in 31 CFR part 10 and reprinted them as Treasury Department Circular No. 230 (Circular 230). These regulations are administered by the IRS Office of Professional Responsibility (OPR).

Section 10.3 of Circular 230 generally authorizes attorneys, certified public accountants, enrolled agents and enrolled actuaries to practice before the IRS. An enrolled agent is defined as an individual enrolled as an agent pursuant to the provisions of Circular 230. The provisions of Circular 230 provide that an individual desiring to become an enrolled agent is eligible for enrollment through either the successful passing of a written examination or through demonstration of sufficient expertise in tax administration based on former employment with the IRS. Specifically, § 10.4(a) authorizes the Director of OPR to grant enrollment to an applicant who demonstrates special competence in tax matters by passing a written examination administered by, or administered under the oversight of, the Director of OPR and who has not engaged in any conduct that would justify the censure, suspension, or disbarment of any practitioner under the provisions of Circular 230. Accordingly, every year OPR develops and administers a Special Enrollment Examination (SEE) that is given to all applicants desiring to become enrolled agents so that they can practice before the IRS. The IRS charged applicants a user fee of \$55 (\$45 if taking the examination in parts) in order to take the 2005 SEE.

Section 10.4(b) authorizes the Director of OPR to grant enrollment for former IRS employees if the former employee meets certain requirements, including length of employment with the IRS and substantive tax expertise. Application for enrollment based on former employment with the IRS must be made within three years from the date of separation from such employment.

Once eligible for enrollment, by either passing the examination or because of former employment with the IRS, an applicant must file an application for enrollment on Form 23, "Application for Enrollment to Practice before the Internal Revenue Service," with the Director of OPR. As part of the application for enrollment process, the applicant must enclose a check or

money order payable to the IRS in the amount set forth on Form 23, which constitutes a fee charged to each applicant for enrollment. The fee is nonrefundable regardless of whether the applicant is granted enrollment. The current user fee for enrollment on the Form 23 (Rev. February 2005) is \$80. The Director of OPR will act upon an application for enrollment and issue an enrollment card to each individual whose application for enrollment to practice before the IRS is approved.

Pursuant to § 10.6(d), each individual, once enrolled, is required to renew the enrollment every three years to maintain an active enrollment to practice before the IRS. In order to qualify for renewal, an applicant must certify the completion of the continuing professional education requirements set forth in § 10.6(e) of Circular 230. A nonrefundable user fee of \$80 is currently charged for each application for renewal of enrollment filed with the Director of OPR on Form 8554, "Application for Renewal of Enrollment to Practice Before the Internal Revenue Service."

Contracting Out of Special Enrollment Examination

OPR has recently contracted out certain functions pertaining to the SEE to a private contractor. The contractor will furnish the resources, facilities, and services necessary to administer the entire SEE program, which includes examination development, administration of SEE, notification to IRS of candidates who took the examination, and the results of the examination. The contractor will receive payment for its services by charging a fee to examination applicants. OPR will, nonetheless, still maintain an oversight role with respect to the SEE. The contractor will collect a user fee on behalf of the IRS based on the full costs incurred by the IRS. These final regulations only establish a user fee with respect to the government costs for overseeing the SEE and do not include any fee that the contractor may charge for its services. Accordingly, while the user fee imposed pursuant to these regulations is less than the user fee that applicants were charged in 2005, the total fee that applicants will be charged is greater. The IRS estimates that the efficiencies resulting from using a contractor will reduce the total fees that would otherwise be charged by the IRS in order to recover the full cost of the IRS administering all aspects of the SEE. Further information about the contracting out of the SEE can be found at <http://www.irs.gov/taxpros/agents/index.html>.

Summary of Comments

The final regulations establish an \$11 per part user fee for the SEE. The final regulations establish separate \$125 user fees for the enrollment and renewal of enrollment process. Most of the comments on the proposed regulations did not favor the higher fees. These comments focused on the increased economic burden on enrolled agents resulting from the higher fees. Several comments also stated that the Request for Proposal (RFP) for the examination implied that the IRS would collect its fee from the amount that the contractor is charging for its services. One comment requested that the IRS publicly release the costing methodology and the schedule for reevaluating the user fees, as well as provide a clarification of the "Special Analyses" section of the preamble. For the following reasons, these final regulations follow the proposed regulations without change.

The OMB Circular requires the IRS to calculate and recover its full cost of providing services under the enrolled agent program. In accordance with the OMB Circular, these final regulations increase the fees to bring them in line with actual costs based upon a recent review of the enrolled agent program. The IRS is in compliance with the OMB Circular in its methodology for computation of the actual cost and will follow the OMB Circular's direction providing for a biennial reevaluation of the fees.

The IRS has determined that the full cost to the IRS of overseeing the SEE is \$11 per part per applicant. This revised user fee reflects the change in IRS costs of administering the examination program as a result of contracting out of the examination to a private contractor. For the first examination cycle (October 5, 2006 to December 1, 2006), the contractor is not collecting any user fee on behalf of the IRS. In future years, consistent with the RFP, the contractor will collect the user fee based on the full costs incurred by the IRS in overseeing the examination, which is separate and distinct from the fee that the contractor is charging for its services.

The IRS has determined that the full cost of administering the enrollment and reenrollment process is \$125 per enrolled agent. Before this final regulation, the most recent increase in user fees for the enrollment and renewal of enrollment process was in September 1995.

The Chief Counsel for Advocacy of the Small Business Administration (SBA) commented that the certification in the proposed regulations regarding

the economic impact on small entities in the "Special Analyses" section of the preamble could be clearer. Specifically, the SBA requested that the certification identify the number of enrolled agents and the appropriate North American Industry Classification System (NAICS) codes for enrolled agents, estimate the percent of enrolled agents that are operating as or employed by small entities based upon the small business size standards established by the SBA, and further explain why the increased fees are not economically significant. The "Special Analyses" section of the final regulations adopts these recommended changes.

Special Analyses

It has been determined that this final rule is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It is hereby certified that these regulations will not have a significant economic impact on a substantial number of small entities. Accordingly, a regulatory flexibility analysis is not required. This certification is based on the information that follows. This final rule affects enrolled agents, of which there are currently 45,261 active. The economic impact of these regulations on any small entity would result from a small entity, including a sole proprietor, being required to pay a fee prescribed by these regulations in order to obtain a particular service. The appropriate NAICS codes for enrolled agents relate to tax preparation services (NAICS code 541213) and other accounting services (NAICS code 541219). Entities identified under these codes are considered small under the SBA size standards (13 CFR 121.201) if their annual revenue is less than \$6.5 million or \$7.5 million respectively. The IRS estimates that 99 percent of enrolled agents are operating as or employed by small entities. Therefore, the IRS has determined that this final rule will affect a substantial number of small entities. The dollar amounts of the increases in fees are not, however, substantial enough to have a significant economic impact on any entity subject to the fees. The amounts of the fees are commensurate with, if not less than, the amount of fees charged for other professional examination and enrollment fees. Persons who elect to take the examination and apply for enrollment or renewal of enrollment also receive benefits from obtaining the enrolled agent designation. The Chief Counsel for Advocacy of the Small Business Administration submitted comments on the regulation, which are discussed elsewhere in this preamble.

Drafting Information

The principal author of these regulations is Matthew S. Cooper of the Office of the Associate Chief Counsel (Procedure & Administration), Administrative Provisions & Judicial Practice Division.

List of Subjects in 26 CFR Part 300

Reporting and recordkeeping requirements, User fees.

Adoption of Amendments to the Regulations

■ Accordingly, 26 CFR part 300 is amended as follows:

PART 300—USER FEES

■ **Paragraph 1.** The authority citation for part 300 continues to read in part as follows:

Authority: 31 U.S.C. 9701.

■ **Par. 2.** Section 300.0 is amended as follows:

■ 1. Paragraphs (b)(4), (b)(5), and (b)(6) are added.

■ 2. Paragraph (c) is revised.

The additions and revision read as follows:

§ 300.0 User fees; in general.

* * * * *

(b) * * *

(4) Taking the special enrollment examination to become an enrolled agent.

(5) Enrolling an enrolled agent.

(6) Renewing the enrollment of an enrolled agent.

(c) *Effective date.* This part 300 is applicable March 16, 1995, except that the user fee for processing offers in compromise is applicable November 1, 2003, and the user fee for the special enrollment examination, enrollment, and renewal of enrollment for enrolled agents is applicable November 6, 2006.

■ **Par. 3.** Section 300.4 is added to read as follows:

§ 300.4 Special enrollment examination fee.

(a) *Applicability.* This section applies to the special enrollment examination to become an enrolled agent pursuant to 31 CFR 10.4(a).

(b) *Fee.* The fee for taking the special enrollment examination is \$11 per part, which is the government cost for overseeing the examination and does not include any fees charged by the examination administrator.

(c) *Person liable for the fee.* The person liable for the special enrollment examination fee is the applicant taking the examination.

■ **Par. 4.** Section 300.5 is added to read as follows:

§ 300.5 Enrollment of enrolled agent fee.

(a) *Applicability.* This section applies to the initial enrollment of enrolled agents with the IRS Office of Professional Responsibility pursuant to 31 CFR 10.5(b).

(b) *Fee.* The fee for initially enrolling as an enrolled agent with the IRS Office of Professional Responsibility is \$125.

(c) *Person liable for the fee.* The person liable for the enrollment fee is the applicant filing for enrollment as an enrolled agent with the IRS Office of Professional Responsibility.

■ **Par. 5.** Section 300.6 is added to read as follows:

§ 300.6 Renewal of enrollment of enrolled agent fee.

(a) *Applicability.* This section applies to the renewal of enrollment of enrolled agents with the IRS Office of Professional Responsibility pursuant to 31 CFR 10.6(d)(6).

(b) *Fee.* The fee for renewal of enrollment as an enrolled agent with the IRS Office of Professional Responsibility is \$125.

(c) *Person liable for the fee.* The person liable for the renewal of enrollment fee is the person renewing their enrollment as an enrolled agent with the IRS Office of Professional Responsibility.

Mark E. Matthews,

Deputy Commissioner for Services and Enforcement.

Approved: October 2, 2006,

Eric Solomon,

Acting Deputy Assistant Secretary for Tax Policy.

[FR Doc. 06-8525 Filed 10-3-06; 10:00 am]

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DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Parts 594, 595, and 597

Global Terrorism Sanctions Regulations; Terrorism Sanctions Regulations; Foreign Terrorist Organizations Sanctions Regulations

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Final rule; amendment.

SUMMARY: The Office of Foreign Assets Control of the U.S. Department of the Treasury ("OFAC") is revising the Global Terrorism Sanctions Regulations, the Terrorism Sanctions Regulations, and the Foreign Terrorist Organizations Sanctions Regulations to authorize in-kind donations of medical devices and