Rm. 5431, Silver Spring MD 20993–0002, or you may send an email request to the Office of Combination Products at *combination@fda.gov.* If you are submitting a written request, send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Lori Churchyard, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911; or Angela Krueger, Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1666, Silver Spring, MD 20993–0002, 301–796–6380; or Leigh Hayes, Office of Combination Products, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5125, Silver Spring, MD 20993–0002, 301–796–8938.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Homologous Use of Human Cells, Tissues, and Cellular and Tissue-Based Products; Draft Guidance for Industry and FDA Staff.'' The draft guidance document provides HCT/P manufacturers, health care providers, and FDA staff, with recommendations for applying the § 1271.10(a)(2) (21 CFR 1271.10(a)(2)) criterion of homologous use. This guidance will improve stakeholders' understanding of the definition of homologous use in § 1271.3(c), and how to apply the regulatory criterion in § 1271.10(a)(2) to their HCT/P.

HCT/Ps are defined in § 1271.3(d) as articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient. FDA has implemented a risk-based approach to the regulation of HCT/Ps. Under the authority of section 361 of the Public Health Service (PHS) Act (42 U.S.C. 264), FDA established regulations under part 1271 for all HCT/Ps to prevent the introduction, transmission, and spread of communicable diseases. HCT/Ps are regulated solely under section 361 of the PHS Act and 21 CFR part 1271, if they meet the criteria provided under § 1271.10(a).

If an HCT/P does not meet all of the criteria set out under § 1271.10(a), and does not meet one of the exceptions in § 1271.15, the HCT/P will be regulated as a drug, device, and/or biological product under the Federal Food, Drug, and Cosmetic Act, and/or section 351 of the PHS Act (42 U.S.C. 262).

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on ''Homologous Use of Human Cells, Tissues, and Cellular and Tissue-Based Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirement of the applicable statutes and regulations.

In a separate document published elsewhere in this issue of the **Federal Register**, FDA is announcing a public hearing entitled ''Draft Guidances Relating to the Regulation of Human Cells, Tissues or Cellular or Tissue-Based Products; Public Hearing; Request for Comments'' to be held on April 13, 2016, to provide stakeholders with the opportunity to discuss FDA's policy on regulation of HCT/Ps related to the four draft guidances on the following topics: Homologous use, same surgical procedure exception, minimal manipulation, and adipose tissue.

In separate documents published elsewhere in this issue of the **Federal Register**, FDA is also reopening the comment periods to FDA's public dockets on the previously issued draft guidance documents on the following topics related to HCT/Ps: Minimal manipulation (Docket No. FDA–2014–D–1696), adipose tissue (Docket No. FDA–2014–D–1856), and same surgical procedure exception (Docket No. FDA–2014–D–1584).

II. Paperwork Reduction Act of 1995

The draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 1271 have been approved under OMB control number 0910–0543.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm* or *http://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/default.htm* or *http://www.regulations.gov.* Persons unable to download an electronic copy of the draft guidance entitled ''Homologous Use of Human Cells, Tissues, and Cellular and Tissue-Based Products; Draft Guidance for Industry and FDA Staff'' may send an email request to *CDRH-guidance@fda.hhs.gov* to receive an electronic copy of the document.

Dated: October 27, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–27704 Filed 10–29–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 300

[REG–121496–15]

RIN 1545–BN02

Preparer Tax Identification Number (PTIN) User Fee Update

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations.

SUMMARY: In the Rules and Regulations section of this issue of the **Federal Register**, the IRS is issuing temporary regulations that will amend regulations (TD 9503) relating to the imposition of certain user fees on tax return preparers. The temporary regulations reduce the amount of the user fee to apply for or renew a preparer tax identification number (PTIN). The text of the temporary regulations also serves as the text of these proposed regulations.

DATES: Written or electronic comments and requests for a public hearing must be received by January 28, 2016.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–121496–15), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–121496–15), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC 20224 or sent electronically via the Federal eRulemaking Portal at *http://*

www.regulations.gov (IRS REG–121496–15). The public hearing will be held in the Auditorium of the Internal Revenue Building, 1111 Constitution Avenue NW., Washington, DC

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Hollie M. Marx at (202) 317–6844; concerning cost methodology, Eva J. Williams at (202) 803–9728; concerning submission of comments and/or requests for a public hearing, Oluwafunmilayo Taylor, (202) 317–6901 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background and Explanation of Provisions

Temporary regulations in the Rules and Regulations section of this issue of the **Federal Register** amend regulations under 26 CFR part 300 setting a user fee for individuals who apply for or renew a PTIN. The text of the temporary regulations also serves as the text of these proposed regulations. The preamble to the temporary regulations explains the temporary regulations and these proposed regulations.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866, as supplemented by Executive Order 13563.

It has been determined that an initial regulatory flexibility analysis is required for this notice of proposed rulemaking under 5 U.S.C. 603. This analysis is set forth under the heading ''Initial Regulatory Flexibility Analysis.''

Pursuant to section 7805(f), this notice of proposed rulemaking has been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Initial Regulatory Flexibility Analysis

When an agency issues a rulemaking proposal, the Regulatory Flexibility Act (5 U.S.C. chapter 6) (RFA) requires the agency ''to prepare and make available for public comment an initial regulatory flexibility analysis'' that will ''describe the impact of the proposed rule on small entities.'' See 5 U.S.C. 603(a). Section 605 of the RFA provides an exception to this requirement if the agency certifies that the proposed rulemaking will not have a significant economic impact on a substantial number of small entities. A small entity is defined as a small business, small nonprofit organization, or small governmental jurisdiction. See 5 U.S.C. 601(3) through (6). The IRS and the Treasury Department conclude that the proposed rule, if promulgated, may have a significant economic impact on a substantial number of small entities. As a result, an initial regulatory flexibility analysis is required.

Description of the Reasons Why Action by the Agency Is Being Considered

The IRS and the Treasury Department implemented regulatory changes in 2010 that required any individual who prepares or who assists in preparing all or substantially all of a tax return or claim for refund for compensation to obtain a PTIN. Pursuant to the PTIN regulations, only those individuals who apply for and maintain a current PTIN may prepare tax returns and claims for refund for compensation. Because the ability to prepare tax returns and claims for refund for compensation is limited to individuals who have a PTIN, the provision of a PTIN confers a special benefit. The IRS incurs costs associated with processing a PTIN application and providing the special benefit associated with the PTIN. The IRS and Treasury Department initially determined that the full cost of providing the special benefit conferred by a PTIN was $50 for each original application and each annual renewal. In accordance with OMB Circular A–25, the IRS and Treasury conducted a biennial review of the PTIN user fee amount in 2015 and determined that the full cost of providing the special benefit conferred by a PTIN had been reduced to $33 for each original application and each annual renewal.

A Succinct Statement of the Objectives of, and Legal Basis for, the Proposed Rule

The objective of the proposed regulations is to recover the costs to the government associated with providing the special benefit that an individual receives upon applying for or renewing a PTIN. These costs include activities, processes, and procedures related to the electronic and paper registration and renewal submissions; tax compliance and background checks; professional designation checks; foreign preparer processing; compliance and complaint activities; information technology and contract-related expenses; and communications. The PTIN user fee also takes into account various indirect program costs, including management and support costs. OMB Circular A–25 encourages user fees when special benefits are conferred on identifiable recipients. Individuals who obtain a PTIN receive the ability to prepare or assist in preparing all or substantially all of a tax return or claim for refund for compensation. The ability to prepare or assist in preparing all or substantially all of a tax return or claim for refund for compensation is a special benefit.

The legal basis for the PTIN user fee is contained in section 9701 of title 31.

A Description of and, Where Feasible, an Estimate of the Number of Small Entities to Which the Proposed Rule Will Apply

The proposed regulations affect all individuals who prepare or assist in preparing all or substantially all of a tax return or claim for refund for compensation. Only individuals, not businesses, can apply for or renew a PTIN. Thus, the economic impact of these regulations on any small entity generally will be a result of an individual tax return preparer who is required to apply for or renew a PTIN owning a small business or a small business otherwise employing an individual tax return preparer who is required to apply for or renew a PTIN.

The appropriate NAICS codes for PTINs are those that relate to tax preparation services (NAICS code 541213), offices of certified public accountants (NAICS code 541211), other accounting services (NAICS code 541219), and offices of lawyers (NAICS code 541110). Entities identified as tax preparation services, offices of certified public accountants, and other accounting services are considered small under the Small Business Administration size standards (13 CFR 121.201) if their annual revenue is less than $20.5 million. Entities identified as offices of lawyers are considered small under the Small Business Administration size standards if their annual revenue is less than $11 million. The IRS estimates that approximately 70 to 80 percent of the individuals subject to these proposed regulations are tax return preparers operating as or employed by small entities.

A Description of the Projected Reporting, Recordkeeping and Other Compliance Requirements of the Proposed Rule, Including an Estimate of the Classes of Small Entities Which Will be Subject to the Requirement and the Type of Professional Skills Necessary for Preparation of the Report or Record

No reporting or recordkeeping requirements are projected to be associated with this proposed regulation.

An Identification, to the Extent Practicable, of all Relevant Federal Rules Which May Duplicate, Overlap, or Conflict With the Proposed Rule

The IRS is not aware of any Federal rules that duplicate, overlap, or conflict with the proposed rule.

A Description of Any Significant Alternatives to the Proposed Rule Which Accomplish the Stated Objectives of Applicable Statutes and Which Minimize Any Significant Economic Impact of the Proposed Rule on Small Entities

The IOAA authorizes the charging of user fees for agency services, subject to policies designated by the President. OMB Circular A–25 implements presidential policies regarding user fees and encourages user fees when a government agency provides a special benefit to a member of the public. In the IOAA, Congress has stated a preference that special benefits be self-sustaining.

A PTIN is required for an individual to prepare or assist in preparing all or substantially all of a tax return or claim for refund for compensation. PTINs are used by the IRS to collect and track data on tax return preparers. This data allows the IRS to track the number of persons who prepare or assist in preparing returns and claims for refund, the qualifications of those persons who prepare or assist in preparing returns and claims for refund, the number of returns each person prepares, and, when instances of misconduct or potential misconduct are detected, locate and review returns and claims for refund prepared by a specific tax return preparer. PTINs must be renewed annually to ensure that the identifying information associated with a PTIN is current.

Due to the costs to the government to process the application for a PTIN, the requirement to include a PTIN on tax returns and claims for refund, and the expressed preference in the IOAA that special benefits be self-sustaining, there is no viable alternative to imposing a user fee.

Comments and Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written (a signed original and eight (8) copies) or electronic comments that are submitted timely to the IRS. The IRS and Treasury Department request comments on all aspects of these proposed regulations. All comments that are submitted by the public will be made available for public inspection and copying. A public hearing will be scheduled if requested in writing by any person who timely submits written comments. If a public hearing is scheduled, notice of the date, time, and place for the public hearing will be published in the **Federal Register**.

Drafting Information

The principal author of these regulations is Hollie M. Marx, Office of the Associate Chief Counsel (Procedure and Administration).

List of Subjects in 26 CFR Part 300

Reporting and recordkeeping requirements, User fees.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 300 is proposed to be amended as follows:

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

Authority: 31 U.S.C. 9701.

■ **Par. 2.** Section 300.13 is amended by revising paragraphs (b) and (d) to read as follows:

§ 300.13 Fee for obtaining a preparer tax identification number.

* * * * *

(b) [The text of proposed § 300.13(b) is the same as the text of § 300.13T(b) published elsewhere in this issue of the ***Federal Register****].*

* * * * *

(d) [The text of proposed § 300.13(d) is the same as the text of § 300.13T(d) published elsewhere in this issue of the ***Federal Register****].*

Karen M. Schiller,

Acting Deputy Commissioner for Services and Enforcement.

[FR Doc. 2015–27791 Filed 10–29–15; 8:45 am]

BILLING CODE 4830–01–P

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

29 CFR Part 1635

RIN 3046–AB02

Genetic Information Nondiscrimination Act of 2008

AGENCY: Equal Employment Opportunity Commission.

ACTION: Proposed rule.

SUMMARY: The Equal Employment Opportunity Commission (''EEOC'' or ''Commission'') is issuing a proposed rule that would amend the regulations implementing Title II of the Genetic Information Nondiscrimination Act of 2008 as they relate to employer wellness programs. The proposed regulations address the extent to which an employer may offer an employee inducements for the employee's spouse who is also a participant in the employer's health plan to provide information about the spouse's current or past health status as part of a health risk assessment administered in connection with the employer's offer of health services as part of an employer-sponsored wellness program. Several technical changes to the existing regulation are also proposed.

DATES: Comments regarding this proposal must be received by the Commission on or before December 29, 2015. Please see the section below entitled **ADDRESSES** and **SUPPLEMENTARY INFORMATION** for additional information on submitting comments.

ADDRESSES: You may submit comments, identified by *RIN number* 3046–AB02, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *FAX:* (202) 663–4114. (There is no toll free FAX number). Only comments of six or fewer pages will be accepted via FAX transmittal, in order to assure access to the equipment. Receipt of FAX transmittals will not be acknowledged, except that the sender may request confirmation of receipt by calling the Executive Secretariat staff at (202) 663–4070 (voice) or (202) 663–4074 (TTY). (These are not toll free numbers).
- *Mail:* Bernadette Wilson, Acting Executive Officer, Executive Secretariat, Equal Employment Opportunity Commission, U.S. Equal Employment Opportunity Commission, 131 M Street NE., Washington, DC 20507.
- *Hand Delivery/Courier:* Bernadette Wilson, Acting Executive Officer, Executive Secretariat, Equal Employment Opportunity Commission, U.S. Equal Employment Opportunity Commission, 131 M Street NE., Washington, DC 20507.

Instructions: The Commission invites comments from all interested parties. All comment submissions must include the agency name and docket number or the Regulatory Information Number (RIN) for this rulemaking. Comments need be submitted in only one of the above-listed formats. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information you provide.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.* Copies of the received comments also will be available for review at the Commission's library, 131 M Street NE., Suite 4NW08R, Washington, DC 20507, between the hours of 9:30 a.m. and 5:00 p.m., from December 29, 2015 until the Commission publishes the rule in final form.