

unapproved status on labeling. Subsequently, section 302 of the Animal Drug and Animal Generic Drug User Fee Amendments of 2018 (User Fee Amendments of 2018; Pub. L. 115–234) amended the required labeling statement found in section 572(h)(1) of the FD&C Act (21 U.S.C. 360ccc–1(h)(1)) to reinforce that indexed products are legally marketed.

The User Fee Amendments of 2018 also amended the required label statements found in section 572(h)(2) of the FD&C Act regarding, except for use in a non-food early life stage, the prohibition of indexed drugs for use in food-producing animals.

At this time, we are revising the animal drug regulations at § 516.155 (21 CFR 516.155) for labeling of indexed drugs to reflect the amendments made by the User Fee Amendments of 2018 to section 572(h) of the FD&C Act.

**II. Paperwork Reduction Act**

The labeling statements required under section 572(h) of the FD&C Act, as reflected in § 516.155, are public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public (5 CFR 1320.3(c)(2)); therefore, they are exempt from the Office of Management and Budget review and approval under the Paperwork Reduction Act.

**III. Legal Authority**

This final rule sets forth a technical amendment to the regulations to improve the accuracy and completeness of the regulations, and as such does not impose any burden on regulated entities. Although denominated a rule pursuant to the FD&C Act, this document does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a “rule of particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801 through 808. Likewise, this is not a rule subject to Executive Order 12866, which defines a rule as “an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency.”

**List of Subjects in 21 CFR Part 516**

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner

of Food and Drugs, 21 CFR part 516 is amended as follows:

**PART 516—NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES**

■ 1. The authority citation for part 516 continues to read as follows:

Authority: 21 U.S.C. 360ccc–1, 360ccc–2, 371.

■ 2. In § 516.155, revise paragraphs (a) and (b) to read as follows:

**§ 516.155 Labeling of indexed drugs.**

(a) The labeling of an indexed drug that is found to be eligible for indexing under § 516.129(c)(7)(i) shall state, prominently and conspicuously: “LEGAL STATUS—In order to be legally marketed, a new animal drug intended for a minor species must be Approved, Conditionally Approved, or Indexed by the Food and Drug Administration. THIS PRODUCT IS INDEXED—MIF # (followed by the applicable minor species index file number and a period).” “Extra-label use is prohibited.” “This product is not to be used in animals intended for use as food for humans or food-producing animals.”

(b) The labeling of an indexed drug that is found to be eligible for indexing for use in an early, non-food life stage of a food-producing minor species animal, under § 516.129(c)(7)(ii), shall state, prominently and conspicuously: “LEGAL STATUS—In order to be legally marketed, a new animal drug intended for a minor species must be Approved, Conditionally Approved, or Indexed by the Food and Drug Administration. THIS PRODUCT IS INDEXED—MIF # (followed by the applicable minor species index file number and a period).” “Extra-label use is prohibited.”

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Dated: May 9, 2024.

**Lauren K. Roth,**  
*Associate Commissioner for Policy.*

[FR Doc. 2024–10602 Filed 5–14–24; 8:45 am]

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**DEPARTMENT OF THE TREASURY**

**Internal Revenue Service**

**26 CFR Part 300**

[TD 9997]

**RIN 1545–BQ77, 1545–BQ78**

**Preparer Tax Identification Number (PTIN) User Fee Update**

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Final rule.

**SUMMARY:** This document contains final regulations relating to the imposition of certain user fees on tax return preparers. The final regulations adopt without change the text of interim final and proposed regulations that reduced the user fee to apply for or renew a preparer tax identification number (PTIN) from \$21 to \$11. The final regulations affect individuals who apply for or renew a PTIN. The Independent Offices Appropriation Act of 1952 authorizes the charging of user fees.

**DATES:**

*Effective date:* These regulations are effective on June 14, 2024.

*Applicability date:* For date of applicability, see § 300.11(d).

**FOR FURTHER INFORMATION CONTACT:**

Concerning the final regulations, Jamie Song at (202) 317–6845; concerning cost methodology, Michael A. Weber at (202) 803–9738 (not toll-free numbers).

**SUPPLEMENTARY INFORMATION:**

**Background**

This document contains amendments to 26 CFR part 300—User Fees. On October 4, 2023, the Department of the Treasury (Treasury Department) and the IRS published in the **Federal Register** (88 FR 68525) a notice of proposed rulemaking (proposed regulations) by cross-reference to an interim final rule (REG–106203–23) proposing amendments to regulations under 26 CFR part 300. On the same date, the Treasury Department and the IRS published in the **Federal Register** (88 FR 68456) an interim final rule (TD 9980) that reduced the PTIN user fee from \$21 per application or application for renewal to \$11, plus the fee payable directly to a third-party contractor. The interim final rule and the proposed regulations took into account the February 2023 memorandum opinion of the United States District Court for the District of Columbia in *Steele v. United States*, 657 F.Supp.3d 23 (D.D.C. 2023). The preamble to the interim final rule contains a detailed explanation of the legal background and user fee calculations regarding the amendments to these regulations. No public hearing was requested or held, and no comments were received on the proposed regulations. These final regulations therefore adopt the text of the interim final rule and proposed regulations without change.

**Special Analyses**

*I. Regulatory Planning and Review*

The OMB’s Office of Information and Regulatory Analysis has determined that

these final regulations are not significant and are not subject to review under section 6(b) of Executive Order 12866, as amended.

### II. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (5 U.S.C. chapter 6), it is hereby certified that these final regulations will not have a significant economic impact on a substantial number of small entities. Accordingly, a regulatory flexibility analysis is not required. These 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 have 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 have a PTIN owning a small business or a small business otherwise employing an individual tax return preparer who is required to have a PTIN. The Treasury Department and the IRS estimate that approximately 847,555 individuals will apply annually for an initial or renewal PTIN. Although these regulations will likely affect a substantial number of small entities, the economic impact on those entities is not significant. These regulations establish an \$11 fee per application or application for renewal (plus the fee payable directly to the third-party contractor), which is a reduction from the previously established fee, and will therefore not have a significant economic impact on small entities. Accordingly, a regulatory flexibility analysis is not required.

### III. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a State, local, or Tribal government, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. These final regulations do not include any Federal mandate that may result in expenditures by State, local, or Tribal governments, or by the private sector in excess of that threshold.

### IV. Executive Order 13132: Federalism

Executive Order 13132 (Federalism) prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial, direct compliance costs on State and local governments, and is not required

by statute, or preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the Executive order. These final regulations do not have federalism implications and do not impose substantial direct compliance costs on State and local governments or preempt State law within the meaning of the Executive order.

### V. Submission to Small Business Administration

Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking and the interim final rule that preceded these final regulations was submitted to the Chief Counsel for the Office of Advocacy of the Small Business Administration for comment on its impact on small business. No comments were received on the proposed regulations or the interim final rule.

### VI. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

### Drafting Information

The principal author of these regulations is Jamie Song, Office of the Associate Chief Counsel (Procedure and Administration). Other personnel from the Treasury Department and the IRS participated in the development of the regulations.

### List of Subjects in 26 CFR Part 300

Estate taxes, Excise taxes, Fees, Gift taxes, Income taxes, Reporting and recordkeeping requirements.

### PART 300—USER FEES

■ Accordingly, the interim rule amending 26 CFR part 300, which was published at 88 FR 68456 on October 4, 2023, is adopted as final without change.

**Douglas W. O'Donnell,**

*Deputy Commissioner.*

Approved: April 28, 2024.

**Aviva R. Aron-Dine,**

*Acting Assistant Secretary of the Treasury (Tax Policy).*

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## DEPARTMENT OF THE TREASURY

### Alcohol and Tobacco Tax and Trade Bureau

#### 27 CFR Part 9

[Docket No. TTB-2023-0006; T.D. TTB-194; Re: Notice No. 224]

RIN 1513-AD02

### Establishment of the Upper Cumberland Viticultural Area

**AGENCY:** Alcohol and Tobacco Tax and Trade Bureau, Treasury.

**ACTION:** Final rule; Treasury decision.

**SUMMARY:** The Alcohol and Tobacco Tax and Trade Bureau (TTB) establishes the approximately 2,186,689-acre “Upper Cumberland” American viticultural area (AVA) in Middle Tennessee. The Upper Cumberland viticultural area is not located within, nor does it contain, any other established viticultural area. TTB designates viticultural areas to allow vintners to better describe the origin of their wines and to allow consumers to better identify wines they may purchase.

**DATES:** This final rule is effective June 14, 2024.

**FOR FURTHER INFORMATION CONTACT:** Karen A. Thornton, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW, Box 12, Washington, DC 20005; phone 202-453-1039, ext. 175.

#### SUPPLEMENTARY INFORMATION:

#### Background on Viticultural Areas

##### *TTB Authority*

Section 105(e) of the Federal Alcohol Administration Act (FAA Act), 27 U.S.C. 205(e), authorizes the Secretary of the Treasury to prescribe regulations for the labeling of wine, distilled spirits, and malt beverages. The FAA Act provides that these regulations should, among other things, prohibit consumer deception and the use of misleading statements on labels and ensure that labels provide the consumer with adequate information as to the identity and quality of the product. The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers the FAA Act pursuant to section 1111(d) of the Homeland Security Act of 2002, codified at 6 U.S.C. 531(d). In addition, the Secretary of the Treasury has delegated certain administrative and enforcement authorities to TTB through Treasury Order 120-01.

Part 4 of the TTB regulations (27 CFR part 4) authorizes TTB to establish definitive viticultural areas and regulate