performed, including follow up on the disposition of all positive mammograms and correlation of pathology results with the interpreting physician's mammography report. In addition, for cases of breast cancer among patients imaged at the facility that subsequently become known to the facility, the facility shall promptly initiate follow up on surgical and/or pathology results and review of the mammographic examinations taken prior to the diagnosis of a malignancy. Analysis of these outcome data shall be made individually and collectively for all interpreting physicians and, at a minimum, shall consist of a determination of the following:

(i) Positive predictive value—percent of patients with positive mammograms who are diagnosed with breast cancer within 1 year of the date of the mammographic examination.

(ii) Cancer detection rate—of the patients initially examined with screening mammograms who receive an assessment of ''Incomplete: Need additional imaging evaluation,'' ''Suspicious,'' or ''Highly suggestive of malignancy'' on the screening mammogram or on a subsequent diagnostic mammogram, the number of patients who are diagnosed with breast cancer within 1 year of the date of the initial screening mammogram, expressed arithmetically as a ratio per 1,000 patients.

(iii) Recall rate—percentage of screening mammograms given an assessment of ''Incomplete: Need additional imaging evaluation.''

* * * * *

(j) *Additional mammography review and patient and referring physician notification.*

(1) If FDA or the State certification agency believes that mammographic quality at a facility has been compromised and may present a significant risk to human health, the facility shall provide clinical images and other relevant information, as specified by FDA or the State certification agency, for review by the accreditation body or the State certification agency. This additional mammography review will help FDA or the State certification agency determine whether the facility is in compliance with this section and whether there is a need to notify affected patients, their referring physicians or healthcare providers, and/or the public that there is a significant risk to human health.

(2) Based on the results of the additional mammography review, or other information, FDA or the State certification agency may determine that the quality of mammography performed by a facility, whether or not certified under § 900.11, was so inconsistent with the quality standards established in this part as to present a significant risk to human health. FDA or the State certification agency may require such a facility to notify all patients who received mammograms at the facility or those patients who are determined to be at risk due to the quality of their mammography, and their referring physicians or healthcare providers, of the deficiencies and resulting potential harm, appropriate remedial measures, and such other relevant information as FDA or the State certification agency may require. Such notification shall occur within a timeframe and in a manner specified by FDA or the State certification agency. If the facility is unable or unwilling to perform such notification, FDA or the State certification agency may notify patients and their referring physicians or other healthcare providers individually or through the mass media.

■ 6. In § 900.14, revise paragraph (a) introductory text and paragraphs (a)(3), (5), and (6), and add paragraph (a)(7) to read as follows:

§ 900.14 Suspension or revocation of certificates.

(a) Except as provided in paragraph (b) of this section, FDA may suspend or revoke a certificate if FDA finds, after providing the owner or operator of the facility with notice and opportunity for a hearing in accordance with part 16 of this chapter, that the facility, owner, operator, or any employee of the facility:

* * * * *

(3) Has failed to comply with reasonable requests of FDA, the State certification agency, or the accreditation body for records, information, reports, or materials, including clinical images for an additional mammography review under § 900.12(j), that FDA or the State certification agency believes are necessary to determine the continued eligibility of the facility for a certificate or continued compliance with the standards of § 900.12;

* * * * *

(5) Has violated or aided and abetted in the violation of any provision of or regulation promulgated pursuant to 42 U.S.C. 263b;

(6) Has failed to comply with prior sanctions imposed by FDA or the State certification agency under 42 U.S.C. 263b(h), including a directed plan of correction or a patient and referring physician notification; or

(7) Has failed to comply with reasonable requests of current or former facility personnel for records of their training or experience relevant to their qualification under MQSA, in violation of § 900.12(a)(4).

* * * * *

Dated: March 21, 2018.

Scott Gottlieb,

Commissioner of Food and Drugs.

[FR Doc. 2019–05803 Filed 3–27–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–143686–07]

RIN 1545–BH35

The Allocation of Consideration and Allocation and Recovery of Basis in Transactions Involving Corporate Stock or Securities; Withdrawal

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Proposed rule; withdrawal.

SUMMARY: This document withdraws a notice of proposed rulemaking containing proposed regulations under numerous sections of the Internal Revenue Code (Code). The proposed regulations being withdrawn would have provided guidance on the recovery of stock basis in distributions of property made by a corporation to a shareholder and certain transactions treated as dividend-equivalents, as well as guidance regarding the determination of gain and the basis of stock or securities received in certain transactions. The proposed regulations being withdrawn would have affected shareholders and security holders of corporations.

DATES: As of March 28, 2019, the notice of proposed rulemaking that was published in the **Federal Register** (74 FR 3509) on January 21, 2009, with corrections published in the **Federal Register** (74 FR 9575) on March 5, 2009, is withdrawn.

FOR FURTHER INFORMATION CONTACT: Kevin M. Jacobs at (202) 317–5332 or Aglaia Ovtchinnikova at (202) 317–6975 (neither a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

On January 21, 2009, the Department of the Treasury (Treasury Department) and the IRS published a notice of proposed rulemaking (REG–143686–07)

in the **Federal Register** (74 FR 3509) containing proposed regulations under sections 301, 302, 304, 351, 354, 355, 356, 358, 368, 861, 1001, and 1016 of the Code. On March 5, 2009, the Treasury Department and the IRS published corrections to the notice of proposed rulemaking in the **Federal Register** (74 FR 9575) (collectively, the 2009 Proposed Regulations).

The 2009 Proposed Regulations generally would have provided a single model for stock basis recovery by a shareholder that receives a distribution to which section 301 applies and a single model for sale and exchange transactions to which section 302(a) applies, including certain elements of an exchange in pursuance of a plan of reorganization under section 368. The 2009 Proposed Regulations also would have defined the scope of the exchange that must be analyzed under particular Code provisions and provided a methodology for determining gain under section 356 and stock basis under section 358.

The 2009 Proposed Regulations responded to comments received by the Treasury Department and the IRS regarding the then-recently published section 358 regulations. These comments included suggestions to expand the tracing rules of the section 358 regulations to stock transfers that are subject to section 351 but do not qualify as reorganizations, as well as questions regarding whether (and, if so, to what extent) shareholder elections constitute terms of an exchange and whether the terms of an exchange control for purposes of qualifying a transaction as a reorganization under section 368.

Finally, the 2009 Proposed Regulations included amendments to the current regulations under section 304 that would have updated those regulations to reflect statutory amendments to that section. See section 226 of the Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. 97–248 (96 Stat. 325, 490) (September 3, 1982), section 712(l) of the Deficit Reduction Act of 1984, Pub. L. 98–369 (98 Stat. 494, 953–55) (July 18, 1984), section 1875(b) of the Tax Reform Act of 1986, Pub. L. 99–514 (100 Stat. 2085, 2894) (October 22, 1986), and section 1013 of the Taxpayer Relief Act of 1997, Pub. L. 105–34 (111 Stat. 788, 918) (August 5, 1997).

The Treasury Department and the IRS received many comments regarding the 2009 Proposed Regulations. The chief concern raised by commenters was that the approach taken in the 2009 Proposed Regulations represented an unwarranted departure from current law as a result of which minor changes to an overall business transaction could cause meaningful changes to the tax consequences, thereby elevating the form of the transaction over its substance.

After thoroughly considering the comments received, the Treasury Department and the IRS have determined that it is unlikely that the approach of the 2009 Proposed Regulations can be implemented in comprehensive final regulations without significant modifications. As a result, the Treasury Department and the IRS have decided to withdraw the 2009 Proposed Regulations. The Treasury Department and the IRS are continuing to study the issues addressed in the 2009 Proposed Regulations, with a particular focus on issues surrounding sections 301(c)(2) and 304, and § 1.302–2(c) of the Income Tax Regulations.

The Treasury Department and the IRS continue to believe that under current law, the results of a section 301 distribution should derive from the consideration received by a shareholder in respect of each share of stock, notwithstanding designations otherwise. See *Johnson* v. *United States,* 435 F.2d 1257 (4th Cir. 1971). The Treasury Department and the IRS also continue to believe that, under current law, with respect to redemptions governed by section 302(d), any unrecovered basis in the redeemed stock of a shareholder may be shifted to other stock only if such an adjustment is a proper adjustment within the meaning of § 1.302–2(c). Not all shifts of a redeemed shareholder's unrecovered basis result in proper adjustments, and certain basis adjustments can lead to inappropriate results. See, *e.g.,* Notice 2001–45, 2001–33 I.R.B. 129.

Drafting Information

The principal author of this withdrawal notice is Aglaia Ovtchinnikova of the Office of Associate Chief Counsel (Corporate). However, other personnel from the Treasury Department and the IRS participated in its development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Withdrawal of Notice of Proposed Rulemaking

■ Accordingly, under the authority of 26 U.S.C. 7805, the Treasury Department and the IRS withdraw the notice of proposed rulemaking (REG–143686–07) that was published in the **Federal Register** (74 FR 3509) on January 21, 2009, with corrections that were published in the **Federal Register** (74 FR 9575) on March 5, 2009.

Kirsten Wielobob,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 2019–05959 Filed 3–27–19; 8:45 am]

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DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Parts 4, 5, 7, 14, and 19

[Docket No. TTB–2018–0007; Notice No. 176]

RIN 1513–AB54

Modernization of the Labeling and Advertising Regulations for Wine, Distilled Spirits, and Malt Beverages

Correction

In proposed rule 2018–24446 beginning on page 60562 in the issue of Monday, November 26, 2018, make the following corrections:

1. On page 60616, in the second column, section heading ''§ 4.04.0 Scope.'' should read ''§ 4.0 Scope.''.

2. On the same page, in the same column, section heading ''§ 4.14.1 Definitions.'' should read ''§ 4.1 Definitions.''.

3. On page 60617, in the first column, section heading ''§ 4.24.2 Territorial extent.'' should read ''§ 4.2 Territorial extent.''.

4. On the same page, in the same column, section heading ''§ 4.34.3 General requirements and prohibitions under the FAA Act.'' should read ''§ 4.3 General requirements and prohibitions under the FAA Act.''.

5. On the same page, in the third column, section heading ''§ 4.44.4 [Reserved]'' should read ''§ 4.4 [Reserved]''.

6. On the same page, in the same column, section heading ''§ 4.54.5 Wines covered by this part.'' should read ''§ 4.5 Wines covered by this part.''.

7. On the same page, in the same column, section heading ''§ 4.64.6 Products produced as wine that are not covered by this part.'' should read ''§ 4.6 Products produced as wine that are not covered by this part.''.

8. On the same page, in the same column, section heading ''§ 4.74.7 Other TTB labeling regulations that apply to wine.'' should read ''§ 4.7 Other TTB labeling regulations that apply to wine.''.

9. On page 60618, in the first column, section heading ''§ 4.84.8 Wine for