

228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 2, 2005, 70 FR 45273 (August 5, 2005).

#### Supplement No. 1 to Part 774 [Corrected]

■ 2. In Supplement No. 1 to part 774 (the Commerce Control List), Category 4—Computers, Export Control Classification Number (ECCN) 4E001 the “TSR” paragraph of the License Exceptions section, and the “items” paragraph in the List of Items Controlled section, are corrected to read as follows:

**4E001 “Technology” according to the General Technology Note, for the “development”, “production” or “use” of equipment or “software” controlled by 4A (except 4A980, 4A993 or 4A994) or 4D (except 4D980, 4D993, 4D994), and other specified technology, see List of Items Controlled.**

\* \* \* \* \*

#### License Exceptions

CIV: \* \* \*

TSR: Yes, except technology for commodities controlled by ECCN 4A003.b or ECCN 4A003.c is limited to technology for computers or electronic assemblies with an “Adjusted Peak Performance” (“APP”) not exceeding 0.1 Weighted TeraFLOPS (WT).

APP: \* \* \*.

#### List of Items Controlled

Unit: \* \* \*

Related Controls: \* \* \*

Related Definitions: \* \* \*

Items:

a. “Technology” according to the General Technology Note, for the “development,” “production,” or “use” of equipment or “software” controlled by 4A (except 4A980, 4A993 or 4A994) or 4D (except 4D980, 4D993, 4D994).

b. “Technology”, other than that controlled by 4E001.a, specially designed or modified for the “development” or “production” of:

b.1. “Digital computers” having an “Adjusted Peak Performance” (“APP”) exceeding 0.04 Weighted TeraFLOPS (WT); or

b.2. “Electronic assemblies” specially designed or modified for enhancing performance by aggregation of processors so that the “APP” of the aggregation exceeds the limit in 4E001.b.1.

Dated: April 27, 2006.

**Eileen M. Albanese,**

*Director, Office of Exporter Services.*

[FR Doc. 06–4123 Filed 5–1–06; 8:45 am]

**BILLING CODE 3510–33–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 210

[Docket No. 2005N–0285]

### Current Good Manufacturing Practice Regulation and Investigational New Drugs; Withdrawal

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Direct final rule; withdrawal.

**SUMMARY:** The Food and Drug Administration (FDA) is withdrawing the direct final rule that published in the **Federal Register** of January 17, 2006, to amend its current good manufacturing practice (CGMP) regulations for human drugs, including biological products, to exempt most investigational “Phase 1” drugs from complying with the requirements in FDA’s regulations. FDA is withdrawing the rule because significant adverse comments were received.

**DATES:** The revision of 21 CFR part 210, published at 71 FR 2458 (January 17, 2006), is withdrawn as of May 2, 2006.

#### FOR FURTHER INFORMATION CONTACT:

Monica Caphart, Center for Drug Evaluation and Research (HFD–320), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–9047, or

Christopher Joneckis, Food and Drug Administration, Center for Biologics Evaluation and Research (HFM–1), 1401 Rockville Pike, Rockville, MD 20852, 301–435–5681.

**SUPPLEMENTARY INFORMATION:** FDA published a direct final rule on January 17, 2006 (71 FR 2458), that was intended to revise the current good manufacturing practice (CGMP) regulations for human drugs, including biological products, to exempt most investigational “Phase 1” drugs from complying with the requirements in FDA’s regulations. In response to the direct final rule, the agency received significant adverse comments about the proposed revisions to the rule.

Under FDA’s direct final rule procedures, the receipt of any significant adverse comment will result in the withdrawal of the direct final rule. Thus, this direct final rule is being withdrawn, effective immediately. Comments received by the agency regarding the withdrawn rule will be considered in developing a final rule using the usual Administrative Procedure Act notice-and-comment procedures.

For the reasons set forth in the preamble of this notice, and under the authority of the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, the revision of 21 CFR part 210, published at 71 FR 2458 (January 17, 2006), is withdrawn.

Dated: April 25, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 06–4091 Filed 5–1–06; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Part 1

[TD 9253]

**RIN 1545–AY92**

### Revisions to Regulations Relating to Withholding of Tax on Certain U.S. Source Income Paid to Foreign Persons and Revisions of Information Reporting Regulations; Correction

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

**ACTION:** Correcting amendment.

**SUMMARY:** This document corrects final regulations and removal of temporary regulations (TD 9253) that was published in the **Federal Register** on Tuesday, March 14, 2006 (71 FR 13003) relating to the withholding of tax under section 1441 on certain U.S. source income paid to foreign persons and related requirements governing collection, deposit, refunds, and credits of withheld amounts under sections 1461 through 1463.

**DATES:** This correction is effective March 14, 2006.

**FOR FURTHER INFORMATION CONTACT:** Ethan Atticks, (202) 622–3840 (not a toll-free number).

#### SUPPLEMENTARY INFORMATION:

#### Background

The final regulations and removal of temporary regulations (TD 9253) that is the subject of this correction are under section 1441 of the Internal Revenue Code.

#### Need for Correction

As published, TD 9253 contains an error that may prove to be misleading and is in need of clarification.

#### List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

## Correction of Publication

■ Accordingly, 26 CFR part 1 is corrected by making the following correcting amendment:

### PART 1—INCOME TAXES

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

Authority: 26 U.S.C. 7805 \* \* \*

#### § 1.1441–6 [Corrected]

■ **Par. 2.** Section 1.1441–6(b)(1) is amended by removing the language “If the beneficial owner is related to the person obligated to pay the income, within the meaning of section 267(b) or 707(b), the withholding certificate must also contain a representation that the beneficial owner will file the statement required under § 301.6114–1(d) of this chapter (if applicable). The requirement to file an information statement under section 6114 for income subject to withholding applies only to amounts received during the taxpayer’s taxable year that, in the aggregate, exceed \$500,000. See § 301.6114–1(d) of this chapter.”.

Guy R. Traynor,

Chief, Publications and Regulations Branch,  
Legal Processing Division, Associate Chief  
Counsel (Procedure and Administration).

[FR Doc. 06–4088 Filed 5–1–06; 8:45 am]

BILLING CODE 4830–01–P

## DEPARTMENT OF THE TREASURY

### Alcohol and Tobacco Tax and Trade Bureau

#### 27 CFR Part 4

[T.D. TTB–45; Re: Notice No. 49]

RIN 1513–AB11

#### Change to Vintage Date Requirements (2005R–212P)

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

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

**SUMMARY:** The Alcohol and Tobacco Tax and Trade Bureau is adopting as a final rule, with some changes, a proposed amendment to the regulations pertaining to wine vintage date labeling.

**DATES:** *Effective date:* June 1, 2006.

**FOR FURTHER INFORMATION CONTACT:** Marjorie D. Ruhf, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street, NW., Washington, DC 20220; telephone 202–927–8202.

**SUPPLEMENTARY INFORMATION:**

## Background on Wine Labeling

### TTB Authority

The Federal Alcohol Administration Act (the FAA Act, 27 U.S.C. 201 *et seq.*) gives the Secretary of the Treasury the authority to issue regulations with respect to the labeling and advertising of wines, distilled spirits, and malt beverages. In particular, section 105(e) of the FAA Act, 27 U.S.C. 205(e), provides that such alcohol beverages must be labeled in compliance with regulations that prohibit deception of the consumer, provide the consumer with “adequate information” as to the identity and quality of the product, and prohibit false or misleading statements. The Secretary’s authority to administer these regulations has been delegated to the Alcohol and Tobacco Tax and Trade Bureau (TTB).

### Current Vintage Date Requirements

Part 4 of the TTB regulations (27 CFR part 4) contains the rules governing labeling of wine. The current rules for the use of a vintage date on a wine label are found at 27 CFR 4.27. Section 4.27(a) provides that at least 95 percent of a vintage-dated wine must have been derived from grapes harvested in the calendar year shown on the label and, further, that the wine must be labeled with an appellation of origin other than a country (which does not qualify for vintage labeling).

Before 1972, regulations in part 4 defined the phrase “vintage wine” as wine that was made “wholly from grapes gathered in the same calendar year and grown and fermented in the same viticultural area, and conforming to the standards prescribed in Classes 1, 2, and 3 of § 4.21.” In T.D. 7185 (37 FR 7974), published on April 22, 1972, the Internal Revenue Service (IRS), which administered the FAA Act at the time, amended that definition to allow the addition of up to 5 percent of other wines to vintage wine. An industry association had requested this change in order to allow producers to replace wine lost by evaporation and leakage during the aging period. In adopting the change, the IRS recognized that requiring vintage wine to be derived wholly from grapes gathered in the stated year was “unnecessarily restrictive when viewed in the light of practices in some of the principal wine producing countries of the world.” The IRS also concluded that liberalization of the vintage date regulations “would not be adverse to the consumer interest.”

On August 23, 1978, our predecessor Agency, the Bureau of Alcohol, Tobacco and Firearms (ATF), again amended the vintage date regulations to remove the

requirement that 95 percent of the grapes be grown in the same viticultural area. See T.D. ATF–53 (43 FR 37672). ATF stated, “We concur that the two provisions should be divorced, and that vintage should refer only to the year of harvest. \* \* \* The percentage required to come from the labeled appellation of origin will vary with the type of appellation \* \* \*.”

### Vintage Date Petition

On April 12, 2005, the Wine Institute, a trade association of California wineries, submitted a petition to TTB to amend § 4.27(a) to allow wine labeled with a State, multistate, county, or multicounty appellation of origin (or the foreign equivalent of a State or county) to bear a vintage date if at least 85 percent of the wine is derived from grapes harvested in the labeled calendar year. In the case of wine with an American viticultural area (or its foreign equivalent) as an appellation of origin, the petitioner proposed to retain the current requirement that at least 95 percent of the grapes in a vintage-dated wine be harvested in the year shown on the label. The petitioner noted that TTB already set separate standards for viticultural areas and other appellations of origin with regard to the percentage of grapes that must be grown in the labeled appellation. We note in this regard that, pursuant to 27 CFR 4.25, wine is qualified for a country, State, or county appellation of origin if at least 75 percent of the wine is derived from grapes grown in the labeled area and other conditions are met, while the requirement for viticultural area appellations of origin is 85 percent.

In support of its request, the petitioner provided information on the vintage date labeling requirements of other wine producing countries. According to this material, Australia, New Zealand, and the Member States of the European Union have an 85-percent, same-year content requirement for vintage-dated wine, while Chile and South Africa require only that 75 percent of the grapes in a vintage-dated wine be grown in the year shown on the label. In addition to showing the widespread use of the 85-percent standard in other wine-producing countries, the petitioner stated that the disparity in standards raised a concern that domestic vintage wines may be competing with imported vintage wines that do not conform to the 95-percent standard.

The petitioner asserted that the proposed amendment would benefit both U.S. winemakers and American consumers because of the advantage derived from being able to use either a