DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

21 CFR Part 579
[Docket No. FDA–2012–F–0178]

Irradiation in the Production, Processing, and Handling of Animal Feed and Pet Food; Electron Beam and X-Ray Sources for Irradiation of Poultry Feed and Poultry Feed Ingredients; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Correcting amendments.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document amending the regulations for irradiation of animal feed and pet food that appeared in the Federal Register of May 10, 2013 (78 FR 27303). That document used incorrect style for the strength units describing radiation sources. This correction is being made to improve the accuracy of the animal drug regulations.

List of Subjects in 21 CFR Part 579

Animal feeds, Animal foods, Radiation protection.

Therefore, 21 CFR part 579 is corrected by making the following correcting amendments.

PART 579—IRRADIATION IN THE PRODUCTION, PROCESSING, AND HANDLING OF ANIMAL FEED AND PET FOOD

1. The authority citation for 21 CFR part 579 continues to read as follows:


2. In §579.40, revise paragraphs (a)(2), (a)(3), and (a)(4) to read as follows:

§579.40 Ionizing radiation for the treatment of poultry feed and poultry feed ingredients.

* * * * *

(a) * * *

(2) Electrons generated from machine sources at energy levels not to exceed 10 million electron volts (MeV);

(3) X-rays generated from machine sources at energies not to exceed 5 MeV, except as permitted by §179.26(a)(4) of this chapter; or

(4) X-rays generated from machine sources using tantalum or gold as the target material and using energies not to exceed 7.5 MeV.

* * * * *

Dated: June 4, 2013.

Bernadette Dunham,
Director, Center for Veterinary Medicine.

DEPARTMENT OF THE TREASURY
Alcohol and Tobacco Tax and Trade Bureau

27 CFR Part 4
[Docket No. TTB–2007–0065; T.D. TTB–114; Re: Notice No. 74]

RIN 1513–AB36

Modification of Mandatory Label Information for Wine

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

ACTION: Final rule; Treasury decision.

SUMMARY: The Alcohol and Tobacco Tax and Trade Bureau (TTB) is amending its regulations regarding the mandatory labeling requirements for wine. The regulatory change permits alcohol content to appear on other labels affixed to the container rather than requiring it to appear on the brand label. This regulatory change provides greater flexibility in wine labeling, and will conform the TTB wine labeling regulations to the agreement reached by members of the World Wine Trade Group regarding the presentation of certain information on wine labels.

DATES: Effective Date: August 9, 2013.

FOR FURTHER INFORMATION CONTACT:
Karen Welch, Alcohol and Tobacco Tax and Trade Bureau, Regulations and Rulings Division, 1310 G St. NW., Box 12, Washington, DC 20005; telephone (202) 453–1039, extension 046; or email WineRegs@ttb.gov.

SUPPLEMENTARY INFORMATION:

Background

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, quality, and alcohol content 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). The Secretary has delegated various authorities through Treasury Department Order 120–01 (Revised), dated January 21, 2003, to the TTB Administrator to perform the functions and duties in the administration and enforcement of this law.

Current TTB Mandatory Labeling Requirements for Wine

Part 4 of the TTB regulations (27 CFR part 4) sets forth the requirements under the FAA Act for the labeling and advertising of wine. Section 4.10 (27 CFR 4.10) defines a brand label as the label carrying, in the usual distinctive design, the brand name of the wine. Section 4.32 (27 CFR 4.32) prescribes mandatory label information. Section 4.32(a) requires a statement of the following on the brand label:

- The brand name, in accordance with §4.33;
- The class, type, or other designation, in accordance with §4.34;
- The alcohol content, in accordance with §4.36; and
- On blends consisting of American and foreign wines, if any reference is made to the presence of foreign wine, the exact percentage by volume.

In addition, §4.32(b) lists other mandatory label information that may appear on any label affixed to the container.

World Wine Trade Group Agreement on Requirements for Wine Labeling

The World Wine Trade Group (WWTG) is composed of both government officials and industry representatives from, currently, Argentina, Australia, Canada, Chile, Georgia, New Zealand, South Africa, and the United States. The WWTG was formed to discuss and address issues relating to international wine trade, including reducing and preventing non-tariff barriers to that wine trade.

The Office of the United States Trade Representative heads the inter-agency team from the United States that represents the U.S. Government during WWTG discussions. This team also includes representatives from TTB, the Food and Drug Administration, and the Departments of Commerce, State, and Agriculture.

The WWTG concluded negotiations on a wine labeling agreement intended to facilitate further wine trade among members. The WWTG Agreement on Requirements for Wine Labelling, hereinafter referred to as the “Agreement,” was initiated on September 20, 2006, and was signed in Canberra, Australia, on January 23, 2007, by the United States and other governments. This is an executive agreement and not a treaty. A full copy of the Agreement can be viewed at http://www.ita.doc.gov/td/ocg/WWTGlabel.pdf. These negotiations proceeded from the view that common labeling requirements would provide industry members with the opportunity to use the same label when shipping wine to each of the WWTG member countries.

In the course of the negotiations, the participants recognized that most members consider four particular items of mandatory information. The four items, referred to as “Common Mandatory Information” (hereinafter CMI) in the WWTG Agreement, are: (1) Country of origin, (2) alcohol content (percentage by volume), (3) net contents, and (4) product name. The negotiated Agreement also incorporates a “Single Field of Vision” concept for the placement of the CMI. A “Single Field of Vision” is any part of the surface of the container, excluding its base and cap, that can be seen without having to turn the container. Under this approach, as long as all four of the CMI elements are visible at the same time, they will meet the placement requirements (if any) of each member country. In other words, each country must permit the CMI for an imported wine to appear on any label anywhere on the wine container (except the base or cap), provided all four CMI items are in a Single Field of Vision.

Conforming TTB Regulations to the WWTG Agreement

The United States cannot deposit an instrument of acceptance for the Agreement if the TTB regulations on wine labeling are inconsistent with the CMI terms of the Agreement. TTB reviewed its wine labeling regulations to determine if any change was necessary in order for the United States to meet its obligation to permit these four pieces of information to appear in a single field of vision on labels of imported wines, as outlined in the Agreement. TTB noted that:

- Although the TTB regulations do not require the inclusion of the country of origin on wine labels, such a requirement is contained in statutory and regulatory provisions administered by U.S. Customs and Border Protection (see 19 U.S.C. 1304 and 19 CFR 134.11).
- Consistent with these requirements, the country of origin may appear on any label affixed to a container of imported wine.
- The product name under the Agreement is the word “wine” and the TTB regulations contain no specific requirements for, or restrictions on, the use of the word “wine” alone on wine labels.
- TTB regulations generally allow the net contents statement to appear on any label affixed to the wine container. (See 27 CFR 4.32(b)(2)).
- TTB regulations require that alcohol content information appear on the brand label of a wine container. (See 27 CFR 4.32(a)(3)).

Thus, the only inconsistency between the TTB wine labeling regulations and the CMI terms of the Agreement is in the regulatory requirement for alcohol content information to appear on the brand label. Accordingly, TTB issued a notice of proposed rulemaking in 2007 to propose removing this requirement.

Notice of Proposed Rulemaking and Comments Received

Regulatory Changes Proposed in Notice No. 74

On September 11, 2007, TTB published a notice of proposed rulemaking titled “Modification of Mandatory Label Information for Wine, Distilled Spirits, and Malt Beverages” in the Federal Register (72 FR 51732) as Notice No. 74. In that notice, TTB proposed to permit alcohol content information for wine, distilled spirits, and malt beverages to appear on other labels affixed to the container rather than on the brand label as is currently required. Specifically, TTB proposed to amend 27 CFR 4.32 (mandatory label information for wine), 5.32 (mandatory label information for distilled spirits), and 7.22 (mandatory label information for malt beverages) to move the alcohol content requirements from paragraph (a) of each of those sections, which prescribes in each case mandatory label information required to appear on a brand label, to paragraph (b) of each of those sections, which prescribes mandatory label requirements for information that need not appear on the brand label.

The change in § 4.32 will allow industry members to apply the WWTG “Single Field of Vision” concept concerning the placement of CMI on labels. TTB’s proposal to make the additional changes in §§ 5.32, and 7.22
was intended to foster consistency in the labeling requirements among all TTB-regulated alcohol beverage products. The changes proposed in Notice No. 74 were limited to removing the placement requirement for alcohol content. All other formatting requirements, such as type size and legibility, remain the same.

Comments Received

In Notice No. 74, TTB requested comments from all interested persons on the proposed regulatory changes by November 13, 2007. TTB received five comments in response to that notice. (Copies of Notice No. 74, the comments received, and this final rule are available online at the “Regulations.gov” Web site [http://www.regulations.gov] within Docket No. TTB—2007–0065.)

Three comments expressed support for the proposal. Jackson Family Wines stated its support for the WWTG labeling initiative, as well as for giving industry members more flexibility in labeling while not reducing the information that is available to the consumer. The Francis Ford Coppola Winery and the Niebaum-Coppola Estate Winery also expressed their “full support” of the proposal. Finally, the Distilled Spirits Council of the United States (DISCUS) expressed its support for the increased flexibility that the proposal would provide, in addition to the proposal’s reduction of regulatory conflicts among global trading partners. DISCUS also supported TTB’s proposal to make the change for distilled spirits and malt beverages in addition to wine. DISCUS also referred to other proposals outside the scope of Notice No. 74, which are not addressed in this document.

The two remaining comments were mistakenly submitted in response to Notice No. 74, but they actually related to Notice No. 73 (72 FR 41860), which proposed new requirements relating to alcohol content statements and a “Serving Facts” panel on alcohol beverage labels. Because those comments do not pertain to Notice No. 74, they are also not addressed in this document.

In addition to the five comments submitted in response to Notice No. 74, some comments submitted in response to Notice No. 73 included points that were responsive to Notice No. 74. Many commenters expressed strong opposition to TTB’s proposal to allow alcohol content information to appear on any label rather than to require this information to appear on a “Serving Facts” information panel. The Center for Science in the Public Interest (CSPI) specifically stated that the TTB proposal would obscure information that is of vital importance to consumers of alcohol beverages. According to CSPI, “[c]onsumers should not have to hunt for alcohol-content information that might appear in different locations on different brands and different sizes of thousands of products in the market place.” CSPI further stated:

TTB provides no rationale for not requiring alcohol-content information on the “Serving Facts” label, nor does it provide any research, testing, or human factors analyses to determine the effects on consumers of burying critical alcohol-content information anywhere on product containers. Rather, TTB cites the need to conform to an international trade agreement among wine-producing countries.

Many other commenters, most notably consumers, consumer organizations, and public health and education officials, agreed that consumers should not have to hunt for alcohol content information. Other commenters stated that they believe that the alcohol content should continue to be displayed on the brand label as well as in any “Serving Facts” information panel. For example, the Marin Institute (which has since changed its name to Alcohol Justice) supported a requirement to list the alcohol content for all alcohol beverages on the brand label, as is currently required for distilled spirits, wines with an alcohol content above 14 percent alcohol by volume, and certain flavored malt beverages.

TTB Finding

TTB is finalizing the proposal to amend §4.32 so that the United States’ wine labeling regulations will be consistent with the Agreement. The Agreement entered into force on July 1, 2010. This final rule will allow the United States to deposit its instrument of acceptance.

TTB notes that the change does not require alcohol beverage industry members to make any changes to their current labels because alcohol content information may still be placed on the brand label. The TTB regulations (27 CFR 4.40 and 4.50) generally require that regulated industry members obtain a certificate of label approval (COLA) from TTB prior to the bottling or removal of domestic wines, or prior to the release of imported wines, in containers, from customs custody for consumption. TTB’s position is that a new COLA is not required if the only change made to a wine label appearing on a previously issued COLA is the moving of the alcohol content information to a label other than the brand label.

TTB revisited the changes proposed to §§5.32 and 7.22 (similar changes for distilled spirits and malt beverages) and has decided not to finalize these changes at this time. The proposed changes to §§5.32 and 7.22 remain under consideration. TTB may amend those sections in the future. Accordingly, TTB is adopting the proposed regulatory amendments to §4.32, to conform the regulations to the Agreement, but not the proposed regulatory amendments to §§5.32 or 7.22.

TTB is also making a clarifying change to §4.36 with regard to the use of the type designation “table wine” or “light wine” in lieu of a numerical alcohol content statement. Section 4.34(a) provides that the class of the wine must be stated in conformity with the standards of identity if the wine is defined in subpart C of part 4, except that “table wine” or “light wine” and “dessert wine” need not be designated as such. (A “table wine” or “light wine” is grape wine having an alcohol content of at least 7 percent and no more than 14 percent by volume. A “dessert wine” is grape wine having an alcohol content of more than 14 percent but no more than 24 percent by volume.)

As previously noted, §4.32 provides that alcohol content must be stated on the label in accordance with §4.36. However, §4.36 allows wine with an alcohol content of at least 7 percent and no more than 14 percent by volume to bear the type designation “table wine” or “light wine” in lieu of a numerical alcohol content statement. On the other hand, consistent with §4.34(a), the type designation “table wine” or “light wine” need not appear on the label if the wine is labeled with an alcohol content statement, expressed as a percentage of alcohol by volume.

Accordingly, while the type designation “table wine” or “light wine” may be used in lieu of a numerical alcohol content statement pursuant to §4.36, these designations are not treated as alcohol content statements by the Agreement, which only addresses “actual alcohol content” stated as a percentage of alcohol by volume. The amendment to §4.36 simply clarifies that, pursuant to existing regulations on the placement of class and type designations, the designation “table wine” or “light wine” must appear on the brand label where it is used as a type designation in lieu of a numerical alcohol content statement.
Regulatory Analysis and Notices

Executive Order 12866

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.

Regulatory Flexibility Act

Pursuant to the requirements of the Regulatory Flexibility Act (5 U.S.C. chapter 6), TTB certifies that this rulemaking will not have a significant economic impact on a substantial number of small entities. The rule will not impose, or otherwise cause, a significant increase in reporting, recordkeeping, or other compliance burdens on a substantial number of small entities. The final rule will increase the flexibility afforded to bottlers and importers of wine with regard to placement of mandatory alcohol content statements on labels and will not require any changes to existing labels. Accordingly, a regulatory flexibility analysis is not required.

Paperwork Reduction Act

The collection of information in this rule has been previously approved by the Office of Management and Budget (OMB) under the title "Labeling and Advertising Requirements Under the Federal Alcohol Administration Act," and assigned control number 1513–0087. This regulation will not result in a substantive or material change in the previously approved collection action, nor will it increase the number of information unless it displays a valid OMB control number.

Drafting Information

Karen E. Welch of the Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, drafted this document. Other personnel participated in its development.

List of Subjects in 27 CFR Part 4

Advertising, Customs duties and inspection, Imports, Labeling, Packaging and containers, Reporting and recordkeeping requirements, Trade practices, Wine.

Amendment to the Regulations

For the reasons discussed in the preamble, TTB is amending 27 CFR, chapter I, part 4 as follows:

PART 4—LABELING AND ADVERTISING OF WINE

1. The authority citation for part 4 continues to read as follows:

Authority: 27 U.S.C. 205, unless otherwise noted.

2. In § 4.32:
   a. Paragraph (a)(3) is removed and reserved; and
   b. A new paragraph (b)(3) is added to read as follows:

§ 4.32 Mandatory label information.
   * * * * *
   *(b) * * * *(3) Alcohol content, in accordance with § 4.36.
   * * * * *

3. In § 4.36, paragraph (a) is revised to read as follows:

§ 4.36 Alcoholic content.
   (a) Alcoholic content shall be stated in the case of wines containing more than 14 percent of alcohol by volume. In the case of wine containing 14 percent or less of alcohol by volume, the alcohol content may be stated, but need not be stated if the type designation “table” wine (or “light” wine) appears on the brand label as prescribed in § 4.32(a)(2). Any statement of alcoholic content shall be made as prescribed in paragraph (b) of this section.
   * * * * *

Signed: January 10, 2013.
John J. Manfreda,
Administrator.

Approved: May 23, 2013.
Timothy E. Skud,
Deputy Assistant Secretary (Tax, Trade, and Tariff Policy).

BILLING CODE 4810–31–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2013–0434]

RIN 1625–AA08

Special Local Regulation; Heritage Coast Offshore Grand Prix, Tawas Bay; East Tawas, MI

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary special local regulation on Tawas Bay, Michigan.

This action is necessary and intended to ensure safety of life on the navigable waters immediately prior to, during, and immediately after the Heritage Coast Offshore Grand Prix boat race. This special local regulation will establish restrictions upon, and control movement of, vessels in a portion of Tawas Bay. During the enforcement period, no person or vessel may enter the regulated area without permission of the Captain of the Port.

DATES: This rule is effective from 10 a.m. until 4 p.m. on June 16, 2013.

ADDRESSES: Documents mentioned in this preamble are part of docket [USCG–2013–0434]. To view documents mentioned in this preamble as being available in the docket, go to http://www.regulations.gov, type the docket number in the “SEARCH” box, and click “Search.” You may visit the Docket Management Facility, Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call or email LT Adrian Palomeque, Prevention Department, Sector Detroit, Coast Guard; telephone (313) 568–9508, email Adrian.F.Palomeque@uscg.mil. If you have questions on viewing the docket, call Barbara Hairston, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

DHS Department of Homeland Security
FR Federal Register
NPRM Notice of Proposed Rulemaking

A. Regulatory Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under 5 U.S.C. 553(b)(b), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because doing so would be impracticable and contrary to the public interest. The final details for this power boat race were not known to the Coast Guard until there was