

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 56

[Docket No. FDA-2015-N-5052]

Administrative Actions for Noncompliance; Lesser Administrative Actions; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of August 17, 2016, for the direct final rule that appeared in the **Federal Register** of April 4, 2016. The direct final rule amends the regulations describing lesser administrative actions that may be imposed on an Institutional Review Board (IRB) that has failed to comply with applicable regulations. We are taking this action to ensure clarity and improve the accuracy of the regulations. This document confirms the effective date of the direct final rule.

DATES: Effective date of final rule published in the **Federal Register** of April 4, 2016 (81 FR 19033), confirmed: August 17, 2016.

FOR FURTHER INFORMATION CONTACT: Sheila Brown, Office of Good Clinical Practice, Office of Special Medical Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993-0002, 301-796-6563.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 4, 2016 (81 FR 19033), FDA solicited comments concerning the direct final rule for a 75-day period ending June 20, 2016. FDA stated that the effective date of the direct final rule would be on August 17, 2016, no later than 60 days after the end of the comment period, unless any significant adverse comment was submitted to FDA during the comment period. FDA did not receive any significant adverse comments.

Authority: 21 U.S.C. 321, 343, 346, 346a, 348, 350a, 350b, 351, 352, 353, 355, 360, 360c-360f, 360h, 360i, 360j, 360hh-360ss, 371, 379e, 381; 42 U.S.C. 216, 241, 262. Accordingly, the amendment issued thereby is effective.

Dated: July 15, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-17186 Filed 7-20-16; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 23

[K00103 12/13 A3A10; 134D0102DR-DS5A300000-DR.5A311.IA000113]

RIN 1076-AF25

Indian Child Welfare Act Proceedings

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Announcement of training sessions.

SUMMARY: The Department of the Interior (Department) is hosting training

sessions on its regulations implementing the Indian Child Welfare Act (ICWA) for federally recognized Indian Tribes and for State court and child welfare agency personnel. This document announces the dates and locations of the training sessions.

DATES: See the **SUPPLEMENTARY INFORMATION** section of this document for dates of the training sessions.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section of this document for addresses of the training sessions.

FOR FURTHER INFORMATION CONTACT: Ms. Debra Burton, ICWA Specialist, Office of Indian Services, Bureau of Indian Affairs, (202) 513-7610, debra.burton@bia.gov, or Ms. Elizabeth Appel, Office of Regulatory Affairs & Collaborative Action—Indian Affairs, (202) 273-4680; elizabeth.appel@bia.gov.

SUPPLEMENTARY INFORMATION: On June 14, 2016, the Department published a final rule on Indian Child Welfare Act proceedings, in implementation of ICWA. See 81 FR 38778. To help those affected by the final rule—in particular States courts, State agencies, Tribes, private agencies—to prepare for the December 12, 2016, effective date of the final rule, the Department is offering several training sessions on the final rule.

The following chart shows the current schedule for training sessions. Please check the following Web site for updates: <http://www.bia.gov/WhoWeAre/BIA/OIS/HumanServices/index.htm>. This Web site also includes the training materials and the full text of the regulation.

Date	Time	Type	Location
Monday, August 15, 2016	2:00 p.m.–4:00 p.m. (ET)	Webinar	Please see Web site listed above for call-in and log-in information.
Tuesday, August 16, 2016	2:00 p.m.–4:00 p.m. (ET)	Webinar	Please see Web site listed above for call-in and log-in information.
Thursday, August 18, 2016	8:30 a.m.–4:00 p.m. (Local Time).	On-Site ...	St. Paul, Minnesota—Doubletree St. Paul, 411 Minnesota Street, St. Paul, MN 55101.
Wednesday, August 24, 2016 ...	8:30 a.m.–4:00 p.m. (Local Time).	On-Site ...	Oklahoma City, OK—Supreme Court of Oklahoma, Judicial Center Auditorium, 2100 North Lincoln, Suite 3, Oklahoma City, OK 73105.
Wednesday, September 7, 2016	8:30 a.m.–4:00 p.m. (Local Time).	On-Site ...	Sacramento, CA—Secretary of State Auditorium, 1500 11th Street, Sacramento, CA 95814.
Thursday, September 15, 2016	8:30 a.m.–4:00 p.m. (Local Time).	On-Site ...	Albany, NY—Empire State Plaza Convention Center, Meeting Rooms 2 & 3, Albany, NY 12242.
Thursday, September 22, 2016	8:30 a.m.–4:00 p.m. (Local Time).	On-Site ...	Pierre, SD—Best Western Ramkota Hotel & Convention Center, Amphitheater II, 920 West Sioux Ave., Pierre, SD 57501.
Wednesday, October 5, 2016	8:30 a.m.–4:00 p.m. (Local Time).	On-Site ...	Anchorage, AK—Embassy Suites Hilton, Imagine Ballroom, 600 E. Benson Blvd., Anchorage, AK 99503.
Wednesday, October 19, 2016 ..	8:30 a.m.–4:00 p.m. (Local Time).	On-Site ...	Olympia, WA—Legislative Building on the Capitol Campus, Columbia Room, Sid Snyder and Cherry Lane SW., Olympia, WA 98504-1034.
Wednesday, November 2, 2016	9:30 a.m.–5:00 p.m. (Local Time).	On-Site ...	Phoenix, AZ—Burton Barr Central Library, The Pulliam Auditorium, 1221 N. Central Avenue, Phoenix, AZ 85004.
Tuesday, November 15, 2016 ...	2:00 p.m.–4:00 p.m. (ET)	Webinar	Please see Web site listed above for call-in and log-in information.

Date	Time	Type	Location
Thursday, November 17, 2016 ..	2:00 p.m.–4:00 p.m. (ET)	Webinar	Please see Web site listed above for call-in and log-in information.

At the on-site sessions, trainers will present material during the morning hours, to allow sufficient additional time for discussion.

Each session is open to Tribes, State child welfare agency personnel, and State court personnel. Separate training sessions are being planned for others interested in the new rule and will be announced at a later date. Because space is limited, we ask that you RSVP to comments@bia.gov for each session you plan to attend by submitting your name and the location (or webinar) you plan to attend. Please also note that some on-site locations are at government facilities that may include security screening, and plan accordingly.

Dated: July 13, 2016.

Lawrence S. Roberts,
Acting Assistant Secretary—Indian Affairs.

[FR Doc. 2016–17269 Filed 7–20–16; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Part 9

[Docket No. TTB–2015–0011; T.D. TTB–139;
Ref: Notice No. 155]

RIN 1513–AC22

Establishment of the Tip of the Mitt 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 2,760-square mile “Tip of the Mitt” viticultural area in all or portions of Charlevoix, Emmet, Cheboygan, Presque Isle, Alpena, and Antrim Counties in Michigan. The 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 August 22, 2016.

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). The Secretary of the Treasury has delegated various authorities through Treasury Department Order 120–01, dated December 10, 2013 (superseding Treasury Order 120–01, dated January 24, 2003), to the TTB Administrator to perform the functions and duties in the administration and enforcement of these laws.

Part 4 of the TTB regulations (27 CFR part 4) authorizes TTB to establish definitive viticultural areas and regulate the use of their names as appellations of origin on wine labels and in wine advertisements. Part 9 of the TTB regulations (27 CFR part 9) sets forth standards for the preparation and submission of petitions for the establishment or modification of American viticultural areas (AVAs) and lists the approved AVAs.

Definition

Section 4.25(e)(1)(i) of the TTB regulations (27 CFR 4.25(e)(1)(i)) defines a viticultural area for American wine as a delimited grape-growing region having distinguishing features, as described in part 9 of the regulations, and a name and a delineated boundary, as established in part 9 of the regulations. These designations allow vintners and consumers to attribute a given quality, reputation, or other characteristic of a wine made from grapes grown in an area to the wine’s geographic origin. The

establishment of AVAs allows vintners to describe more accurately the origin of their wines to consumers and helps consumers to identify wines they may purchase. Establishment of an AVA is neither an approval nor an endorsement by TTB of the wine produced in that area.

Requirements

Section 4.25(e)(2) of the TTB regulations (27 CFR 4.25(e)(2)) outlines the procedure for proposing an AVA and provides that any interested party may petition TTB to establish a grape-growing region as an AVA. Section 9.12 of the TTB regulations (27 CFR 9.12) prescribes standards for petitions for the establishment or modification of AVAs. Petitions to establish an AVA must include the following:

- Evidence that the area within the proposed AVA boundary is nationally or locally known by the AVA name specified in the petition;
- An explanation of the basis for defining the boundary of the proposed AVA;
- A narrative description of the features of the proposed AVA affecting viticulture, such as climate, geology, soils, physical features, and elevation, that make the proposed AVA distinctive and distinguish it from adjacent areas outside the proposed AVA boundary;
- The appropriate United States Geological Survey (USGS) map(s) showing the location of the proposed AVA, with the boundary of the proposed AVA clearly drawn thereon; and
- A detailed narrative description of the proposed AVA boundary based on USGS map markings.

Tip of the Mitt Petition

TTB received a petition from the Straits Area Grape Growers Association, on behalf of winery and vineyard owners in the northern portion of Michigan’s Lower Peninsula, proposing the establishment of the “Tip of the Mitt” AVA. The proposed AVA contains approximately 2,760 square miles, and there are 41 commercially-producing vineyards covering a total of 94 acres distributed throughout the proposed AVA, along with 8 wineries. According to the petition, an additional 48 acres of vineyards and 4 new wineries are planned for the near future. The proposed Tip of the Mitt AVA is not located within any established AVA.