

retirement age (age 60 or older). See § 404.1568(d)(4).

■ 3. Amend § 404.1568 to revise the heading and the fifth sentence of paragraph (d)(4) to read as follows:

§ 404.1568 Skill requirements.

(d) *Skills that can be used in other work (transferability).* * * *
 (4) *Transferability of skills for persons of advanced age.* * * * If you are *closely approaching retirement age* (age 60 or older) and you have a severe impairment(s) that limits you to no more than *light* work, we will find that you have skills that are transferable to skilled or semiskilled light work only if the light work is so similar to your previous work that you would need to make very little, if any, vocational adjustment in terms of tools, work processes, work settings, or the industry. * * *

■ 4. Amend part 404, subpart P, appendix 2, as follows:
 ■ a. In section 202.00, revise paragraph (f) to read as follows:
 ■ b. In section 203.00, revise paragraphs (b) and (c) to read as follows:

Appendix 2 to Subpart P of Part 404—Medical-Vocational Guidelines

202.00 *Maximum sustained work capability limited to light work as a result of severe medically determinable impairment(s).*

(f) For a finding of transferability of skills to light work for persons of advanced age who are closely approaching retirement age (age 60 or older), there must be very little, if any, vocational adjustment required in terms of tools, work processes, work settings, or the industry.

203.00 *Maximum sustained work capability limited to medium work as a result of severe medically determinable impairment(s).*

(b) The functional capacity to perform medium work represents such substantial work capability at even the unskilled level that a finding of disabled is ordinarily not warranted in cases where a severely impaired person retains the functional capacity to perform medium work. Even the adversity of advanced age (55 or over) and a work history of unskilled work may be offset by the substantial work capability represented by the functional capacity to perform medium work. However, we will find that a person who (1) has a marginal education, (2) has work experience of 35 years or more doing only arduous unskilled physical labor, (3) is not working, and (4) is no longer able to do

this kind of work because of a severe impairment(s) is disabled, even though the person is able to do medium work. (See § 404.1562(a) in this subpart and § 416.962(a) in subpart I of part 416.)

(c) However, the absence of any relevant work experience becomes a more significant adversity for persons of advanced age (55 and over). Accordingly, this factor, in combination with a limited education or less, militates against making a vocational adjustment to even this substantial range of work and a finding of disabled is appropriate. Further, for persons closely approaching retirement age (60 or older) with a work history of unskilled work and with marginal education or less, a finding of disabled is appropriate.

PART 416—SUPPLEMENTAL SECURITY INCOME FOR THE AGED, BLIND, AND DISABLED

Subpart I—[Amended]

■ 5. The authority citation for subpart I of part 416 continues to read as follows:

Authority: Secs. 221(m), 702 (a)(5), 1611, 1614, 1619, 1631(a), (c), (d)(1), and (p), and 1633 of the Social Security Act (42 U.S.C. 421(m), 902(a)(5), 1382, 1382c, 1382h, 1383(a), (c), (d)(1), and (p), and 1383(b); secs. 4(c) and 5, 6(c)-(e), 14(a), and 15, Pub. L. 98-460, 98 Stat. 1794, 1801, 1802, and 1808 (42 U.S.C. 421 note, 423 note, and 1382h note).

■ 6. Amend § 416.963 to revise paragraph (e) to read as follows:

§ 416.963 Your age as a vocational factor.

(e) *Person of advanced age.* We consider that at advanced age (age 55 or older), age significantly affects a person's ability to adjust to other work. We have special rules for persons of advanced age and for persons in this category who are closely approaching retirement age (age 60 or older). See § 416.968(d)(4).

■ 7. Amend § 416.968 to revise the heading and the fifth sentence of paragraph (d)(4) to read as follows:

§ 416.968 Skill requirements.

(d) Skills that can be used in other work (transferability). * * *
 (4) Transferability of skills for persons of advanced age. * * * If you are *closely approaching retirement age* (age 60 or older) and you have a severe impairment(s) that limits you to no more than *light* work, we will find that you have skills that are transferable to skilled or semiskilled light work only if the light work is so similar to your previous work that you would need to make very little, if any, vocational adjustment in terms of tools, work

processes, work settings, or the industry. * * *

[FR Doc. E8-25532 Filed 10-28-08; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA-2003-F-0398] (formerly Docket No. 2003F-0048)

Food Additives Permitted in Feed and Drinking Water of Animals; Methyl Esters of Conjugated Linoleic Acid (Cis-9, Trans-11 and Trans-10, Cis-12-Octadecadienoic Acids)

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for food additives permitted in feed and drinking water of animals to provide for the safe use of methyl esters of conjugated linoleic acid (cis-9, trans-11 and trans-10, cis-12 octadecadienoic acids) as a source of fatty acids in swine diets. This action is in response to a food additive petition filed by BASF Corp. (BASF), 100 Campus Dr., Florham Park, NJ.

DATES: This rule is effective October 29, 2008. Submit written or electronic objections and requests for a hearing by December 29, 2008. See section V of this document for information on the filing of objections.

ADDRESSES: You may submit objections and a request for a hearing, identified by Docket No. FDA-2003-F-0398, by any of the following methods:

Electronic Submissions

Submit electronic objections in the following way:
 • Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written objections in the following ways:
 • FAX: 301-827-6870.
 • Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of objections, FDA is no longer accepting objections submitted to the agency by e-mail. FDA encourages you to continue to submit electronic objections by using

the Federal eRulemaking Portal, as described previously in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and Docket No(s), and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All objections received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting objections, see the "Objections and Hearing Requests" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or objections received, go to <http://www.regulations.gov> and insert the docket number(s), found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Michaela G. Alewynse, Center for Veterinary Medicine (HFV-228), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6866, e-mail: mika.alewynse@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of March 11, 2003 (68 FR 11567), FDA announced that a food additive petition (animal use) (FAP 2250) had been filed by BASF, 100 Campus Dr., Florham Park, NJ 07932. The petition proposed to amend the food additive regulations to provide for the safe use of methyl esters of conjugated linoleic acid (cis-9, trans-11 and trans-10, cis-12 octadecadienoic acids) as a source of fatty acids in swine diets. The notice of filing provided for a 60-day comment period on the petitioner's environmental information. No comments have been received.

II. Conclusion

FDA concludes that the data establish the safety and utility of methyl esters of conjugated linoleic acid (cis-9, trans-11 and trans-10, cis-12-octadecadienoic acids) for use as proposed with modification and that the food additive regulations should be amended as set forth in this document.

III. Public Disclosure

In accordance with § 571.1(h), the petition and the documents that FDA

considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Veterinary Medicine by appointment with the information contact person. As provided in § 571.1(h), the agency will delete from the documents materials that are not available for public disclosure before making the documents available for inspection.

IV. Environmental Impact

The agency has determined under 21 CFR 25.32(r) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment, nor an environmental impact statement is required.

V. Objections and Hearing Requests

Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (see **ADDRESSES**) written or electronic objections by (see **DATES**). Each objection must be separately numbered, and each numbered objection must specify with particularity the provision of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested must state that a hearing is requested. Failure to request a hearing for any particular objection will constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested must include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection will constitute a waiver of the right to a hearing on the objection. Three copies of all documents must be submitted and must be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 573

Animal feeds, Food additives.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 573 is amended as follows:

PART 573—FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS

■ 1. The authority citation for 21 CFR part 573 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

■ 2. Add § 573.637 to read as follows:

§ 573.637 Methyl esters of conjugated linoleic acid (cis-9, trans-11 and trans-10, cis-12-octadecadienoic acids).

The food additive, methyl esters of conjugated linoleic acid (cis-9, trans-11 and trans-10, cis-12 octadecadienoic acids), may be safely used in swine feed in accordance with the prescribed conditions:

(a) The food additive is manufactured by the reaction of refined sunflower oil with methanol to produce fatty acid methyl esters, which then undergo conjugation to yield methyl esters of octadecadienoic acid. The additive consists of not less than 28 percent methyl ester of cis-9, trans-11-octadecadienoic acid, and not less than 28 percent methyl ester of trans-10, cis-12-octadecadienoic acid with the sum of the other methyl esters of octadecadienoic acid not to exceed 4 percent. The additive shall contain not less than 35 percent of other fatty acid esters composed of oleic acid, palmitic acid, stearic acid, linoleic acid, and other associated acid esters.

(b) The additive is used or intended for use in the feed of growing and finishing swine as a source of fatty acids at levels not to exceed 0.6% in the finished feed.

(c) The additive meets the following specifications:

- (1) Free methyl alcohol not to exceed 0.015%.
- (2) Insoluble impurities not to exceed 0.1%.
- (3) Moisture not to exceed 0.5%.
- (4) Unsaponifiable matter not to exceed 1.0%.

(d) To assure safe use of the additive, in addition to the other information required by the act:

(1) The label and labeling of the additive and any feed premix shall bear the following:

- (i) The name of the additive.
- (ii) A statement to indicate that methyl esters of conjugated linoleic acid (cis-9, trans-11 and trans-10, cis-12 octadecadienoic acids) must not be added to vitamin or mineral premixes.

(2) The label and labeling of the additive, any feed premix, or complete feed prepared therefrom shall bear adequate directions for use.

Dated: October 23, 2008.

William T. Flynn,

Acting Director, Center for Veterinary Medicine.

[FR Doc. E8-25719 Filed 10-28-08; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Part 9

[Docket No. TTB-2007-0066; T.D. TTB-71; Re: Notice No. 76]

RIN 1513-AB49

Establishment of the Leona Valley Viticultural Area (2007R-281P)

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

ACTION: Final rule; Treasury decision.

SUMMARY: This Treasury decision establishes the 13.4-square mile “Leona Valley” American viticultural area in northeastern Los Angeles County, California. We designate 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: *Effective Date:* November 28, 2008.

FOR FURTHER INFORMATION CONTACT: N.A. Sutton, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 925 Lakeville St., No. 158, Petaluma, CA 94952; telephone 415-271-1254.

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 requires that these regulations, 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 regulations promulgated under the FAA Act.

Part 4 of the TTB regulations (27 CFR part 4) allows the establishment of definitive viticultural areas and 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) contains the list of approved viticultural areas.

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 distinguishable by geographical features, the boundaries of which have been recognized and defined 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 its geographical origin. The establishment of viticultural areas allows vintners to describe more accurately the origin of their wines to consumers and helps consumers to identify wines they may purchase. Establishment of a viticultural area 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 outlines the procedure for proposing an American viticultural area and provides that any interested party may petition TTB to establish a grape-growing region as a viticultural area. Section 9.3(b) of the TTB regulations requires the petition to include—

- Evidence that the proposed viticultural area is locally and/or nationally known by the name specified in the petition;
- Historical or current evidence that supports setting the boundary of the proposed viticultural area as the petition specifies;
- Evidence relating to the geographical features, such as climate, soils, elevation, and physical features that distinguish the proposed viticultural area from surrounding areas;
- A description of the specific boundary of the proposed viticultural area, based on features found on United States Geological Survey (USGS) maps; and
- A copy of the appropriate USGS map(s) with the proposed viticultural area’s boundary prominently marked.

Leona Valley Petition

Mr. Ralph Jens Carter submitted a petition for establishment of the 13.4-square mile Leona Valley viticultural area on behalf of the Antelope Valley Winegrowers Association, the Leona Valley Winery, and Donato Vineyards. The area currently includes 20 acres of vineyards, and more acreage for wine grape growing is under development. The proposed Leona Valley viticultural

area boundary line does not affect or overlap any other proposed or established viticultural area.

The proposed boundary line defines an area where viticulture is already established or has potential for establishment. Consequently, the area defined is limited to the valley floor and side slopes. The distinguishing features of the proposed viticultural area include the physical characteristics of the San Andreas Fault system, the fault-controlled Leona Valley, and the surrounding, high-elevation mountains. The climate, geology, and soils distinguish the proposed viticultural area from areas outside of the proposed boundary line.

Name Evidence

According to the petitioner, the name “Leona” derives from an early rancher named Miguel Leonis, and in the 1880s, a homesteader from Nebraska called the area “Leona Valley.” The “Leona Valley” name identifies a valley, a town within the valley, a ranch (the Leona Valley Ranch), and a festival (the annual Leona Valley Cherry Festival).

The petitioner provides maps that show that the Leona Valley is located in the northeast part of Los Angeles County, California. The “Leona Valley” name appears on the USGS Ritter Ridge, Sleepy Valley, and Del Sur quadrangle maps, which the petitioner uses to define the boundary line of the proposed viticultural area. The Sleepy Valley map also identifies a small town in the valley as “Leona Valley.” A recent atlas identifies both a valley and small town within the proposed viticultural area as “Leona Valley” (The DeLorme Southern and Central California Atlas and Gazetteer, 2005, page 79).

Boundary Evidence

According to the petitioner, and as evidenced by the written boundary description and the USGS Sleepy Valley quadrangle map, the proposed viticultural area includes the town and valley which are both named “Leona Valley.” The proposed boundary line borders the Angeles National Forest to the west and the Antelope Valley and the Mojave Desert to the northeast. Mountains and hills surround all sides of the valley. The floor and side slopes of the Leona Valley influence the shape of the proposed viticultural area, which includes vineyards in remote, but suitable, areas, but excludes steep slopes where erosion is a hazard.

According to the petitioner, historically, the Native American Shoshone Tribe lived as hunters and gatherers in the Leona Valley area. In