

separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall 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 shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. This regulation shall become effective May 30, 1984.

(Secs. 210(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348))

Dated: May 17, 1984.

Mark Novitch,

Acting Commissioner of Food and Drugs.

[FR Doc. 84-14387 Filed 5-29-84; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 178

[Docket No. 83F-0264]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

Correction

In FR Doc. 84-11772 beginning on page 18735 in the issue of Wednesday, May 2, 1984, make the following correction:

On page 18736, first column, in the table, under the entry "Substances" fourth line, "B" should have read "β"

BILLING CODE 1505-01-M

21 CFR Part 520

Oral Dosage Form New Animal Drugs Not Subject to Certification; Iodinated Casein Tablets

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to codify a previously approved new animal drug application (NADA) sponsored by Agri-

Tech, Inc. The NADA provides for the use of iodinated casein tablets for use in dogs for decreased thyroid activity manifested by skin and hair coat conditions.

EFFECTIVE DATE: May 30, 1984.

FOR FURTHER INFORMATION CONTACT: Bob Griffith, Center for Veterinary Medicine (formerly Bureau of Veterinary Medicine) (HFV-110), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 301-443-3420.

SUPPLEMENTARY INFORMATION: Agri-Tech, Inc., 4722 Broadway, Kansas City, MO 64112, is the sponsor of NADA 13-502 which provides for use of Protamone-D (iodinated casein) in dogs. The drug is labeled for use in cases of apparent decreased thyroid activity where the signs are alopecia, scaliness of the skin surface, loss of hair, seborrhea, thickening of the skin, hyperpigmentation, and lethargy. The drug was approved by letter dated April 22, 1966.

Approvals at the time were not codified by publication in the Federal Register. This action codifies the previously approved NADA but does not change the approved use of the drug. Because the application was approved before July 1, 1975, the sponsor is not required to submit a summary of the safety and effectiveness data and information under the freedom of information provisions of the animal drug regulations in 21 CFR 514.11(e)(2)(ii). However, a summary of the basis for approval is available upon request in accordance with 21 CFR 514.11(e)(2)(i).

The Center for Veterinary Medicine has determined pursuant to 21 CFR 25.24(d)(1)(i) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 520

Animal drug, Oral use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Veterinary Medicine (21 CFR 5.83), Part 520 is amended by adding new § 520.1157 to read as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

§ 520.1157 Iodinated casein tablets.

(a) *Specifications.* Each 1-gram tablet contains 25 milligrams of iodinated casein.

(b) *Sponsor.* See No. 017762 in § 510.600(c) of this chapter.

(c) *Conditions of use.*—(1) *Amount.* ½ to 1 tablet per 10 pounds of body weight (equivalent to 0.5 to 2.5 milligrams of iodinated casein per pound of body weight).

(2) *Indications for use.* For dogs for apparent decreased thyroid activity where the signs are alopecia, scaliness of the skin surface, loss of hair, seborrhea, thickening of the skin, hyperpigmentation, and lethargy.

(3) *Limitations.* If no response is observed in 30 to 45 days, the drug should be withdrawn and the diagnosis reconsidered. Do not use in the presence of cardiac disease, ischemia, adrenal insufficiency, or nephrosis. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Effective date. May 30, 1984.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

Dated: May 23, 1984.

Lester M. Crawford,

Director, Center for Veterinary Medicine.

[FR Doc. 84-14370 Filed 5-29-84; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 9

[T.D. ATF-176; Reference Notice No. 466]

Altus Viticultural Area

AGENCY: Bureau of Alcohol, Tobacco and Firearms, Department of the Treasury.

ACTION: Final rule (Treasury decision).

SUMMARY: This final rule establishes a viticultural area in Arkansas to be known as "Altus." The Bureau of Alcohol, Tobacco and Firearms believes that the establishment of the Altus viticultural area and the subsequent use of its name in wine labeling and advertising will enable industry to label wines more precisely, and will help consumers to better identify the wines from this area.

EFFECTIVE DATE: June 29, 1984.

FOR FURTHER INFORMATION CONTACT: Steve Simon, FAA, Wine and Beer

Branch, Bureau of Alcohol, Tobacco and Firearms, 1200 Pennsylvania Avenue NW, Washington, DC 20226 (202-566-7626).

SUPPLEMENTARY INFORMATION:

Background

ATF regulations in 27 CFR Part 4 allow the establishment of definite viticultural areas. The regulations also allow the name of an approved viticultural area to be used as an appellation of origin on wine labels and in wine advertisements.

Part 9 of 27 CFR provides for the listing of approved American viticultural areas, the names of which may be used as appellations of origin.

Section 4.25a(e)(1), Title 27 CFR, defines an American viticultural area as a delimited grape-growing region distinguishable by geographical features. Section 4.25a(e)(2) outlines the procedure for proposing an American viticultural area. Any interested person may petition ATF to establish a grape-growing region as a viticultural area.

Petition

ATF received a petition from Mr. Matthew J. Post of the Post Winery, proposing an area near the town of Altus, Arkansas, as a viticultural area to be known as "Altus." In response to this petition, ATF published Notice No. 466 in the Federal Register on Monday, May 16, 1983 (48 FR 21973). This notice solicited public comments in accordance with the Administrative Procedure Act (5 U.S.C. 553). Only two public comments were received. One expressed unqualified support for the proposed area. The other objected to "the deletion of some of our local vineyards from the proposed area." However, this commenter did not respond to requests for an identification of those vineyards or a description of where they are located. Therefore, this Treasury decision establishes the Altus viticultural area with boundaries as proposed in Notice No. 466.

General Information

The Altus viticultural area extends for a length of about five miles, along a plateau situated between the Arkansas River bottomlands and the high peaks of the Boston Mountains. The width of the area is about four miles. The boundaries encompass a total area of between 12,000 and 13,000 acres.

There are about 800 acres planted to grapes on vineyards in the viticultural area. There are four wineries now operating in the area.

Name of the Area

ATF has determined that this viticultural area is known by the name of "Altus" and is associated with grape-growing for the following reasons:

(a) The official stationery of the city of Altus, Arkansas, declares that city to be the "wine capital" of the State.

(b) Wines produced at the area's four wineries (all located within a mile of the Altus Post Office) have won national and international awards.

(c) Labels of all four wineries bear the name "Altus" as part of their mailing address.

(d) Bumper plates used on the first automobiles in town bear the name, "Altus," and the legend, "The grapes grow best."

(e) An article by Joe Crump, entitled "Vintage Memories," appearing in the *Southwest Times Record* of June 25, 1981, discussed "Altus, the village known for its wine."

(f) The stationery of the local St. Joseph's Farmer Club, whose address is Altus, Arkansas, states: "Best flavored grapes grown in the country. Campbell's Early, Delaware and Niagara a specialty."

(g) The Rev. Placidus Oeschle, a local parish priest from 1897 to 1935, wrote the following in 1930, in a work entitled "Historical Sketch of the Congregation of Our Lady of Perpetual Help":

Some of our pioneers came from winemaking countries, and started to plant vineyards. Grape-growing became a very profitable industry, and Altus was soon famous for its good wine.

Our grape festivals are an attraction for thousands of visitors. After many years of experimenting with hundreds of varieties, only a few proved commercially valuable. Today, mostly Campbell's Early, Delaware, Niagara, Brighton, and Banner, and a few others are cultivated for market. The grapes of Altus are famous, and are shipped all over the country.

Geographical Distinctions

ATF has determined that the Altus viticultural area is distinguished from the surrounding area for the following reasons:

(1) The moderating climatological effects of the Boston Mountains protect the area from the harshest of winter's weather.

(2) The elevation of the plateau above the surrounding river and creek valleys creates a microclimate wherein cold air is funneled down to the Arkansas River in the spring and fall. Thus, as the petitioner states, "It has been observed that growers in the hills around Altus enjoy additional frost-free growing days because the colder air sinks to the river

valley, and forces warmer air into the hills in the early spring and late fall."

(3) The soils of the Altus region (known as the Linker-Mountainburg association) are distinctive in that within Arkansas they are found only along the edge of the Boston Mountains. These soils, states the petitioner, "are fine to gravelly in texture, sandy to silty loams, and slightly to strongly acid." These soils are particularly suited to viticulture.

Boundaries

The boundaries of the proposed viticultural area may be found on five U.S.G.S. topographic maps in the 7.5 minute series: Ozark Quadrangle, Coal Hill Quadrangle, Hartman Quadrangle, Hunt Quadrangle, and Watalula Quadrangle. The boundaries are described in § 9.77

Miscellaneous

ATF does not wish to give the impression by approving the Altus viticultural area that it is approving or endorsing the quality of the wine from this area. ATF is approving this area as being distinct from surrounding areas, not better than other areas. By approving the area, wine producers are allowed to claim a distinction on labels and in advertisements as to the origin of the grapes. Any commercial advantage gained can only come from consumer acceptance of the Altus wines.

Regulatory Flexibility Act

The provisions of the Regulatory Flexibility Act relating to an initial and final regulatory flexibility analysis (5 U.S.C. 603, 604) are not applicable to this final rule because it will not have a significant economic impact on a substantial number of small entities. The final rule is not expected to have significant secondary or incidental effects on a substantial number of small entities; or impose, or otherwise cause, a significant increase in the reporting, recordkeeping, or other compliance burdens on a substantial number of small entities.

Accordingly, it is hereby certified under the provisions of Section 3 of the Regulatory Flexibility Act (5 U.S.C. 605(b)), that this final rule will not have a significant economic impact on a substantial number of small entities.

Executive Order 12291

In compliance with Executive Order 12291 of Feb. 17 1981, the Bureau has determined that this final regulation is not a major rule since it will not result in:

- (a) An annual effect on the economy of \$100 million or more;
- (b) A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or
- (c) Significant adverse effects on competition, employment, investment, productivity, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Paperwork Reduction Act

The provisions of the Paperwork Reduction Act of 1980, Pub. L. 96-511, 44 U.S.C. Chapter 35, and its implementing regulations, 5 CFR Part 1320, do not apply to this final rule because no requirement to collect information is imposed.

List of Subjects in 27 CFR Part 9

Administrative practice and procedure, Consumer protection, Viticultural areas, Wine.

Drafting Information

The principal author of this document is Steve Simon, FAA, Wine and Beer Branch, Bureau of Alcohol, Tobacco and Firearms.

Authority and Issuance

Accordingly, under the authority in 27 U.S.C. 205, 27 CFR Part 9 is amended as follows:

PART 9—AMERICAN VITICULTURAL AREAS

Par. 1. The table of sections in 27 CFR Part 9, Subpart C, is revised to add the title of § 9.77 which reads as follows:

* * * * *

Subpart C—Approved American Viticultural Areas

Sec.				
* * *				
9.77	Altus.			
* * *				

Par. 2. Subpart C of 27 CFR Part 9 is amended by adding § 9.77 which reads as follows:

§ 9.77 Altus.

- (a) *Name.* The name of the viticultural area described in this section is "Altus."
- (b) *Approved maps.* The appropriate maps for determining the boundaries of the Altus viticultural area are five U.S.G.S. maps in the 7.5 minute series. They are titled:
 - (1) Ozark Quadrangle, 1966.
 - (2) Coal Hill Quadrangle, 1961.
 - (3) Hartman Quadrangle, 1961.
 - (4) Hunt Quadrangle, 1963.
 - (5) Watalula Quadrangle, 1973.

(c) *Boundary*—(1) *General.* The Altus viticultural area is located in Arkansas. The starting point of the following boundary description is the crossing of the Missouri Pacific Railroad over Gar Creek, near the Arkansas River at the southeast corner of the city of Ozark, Arkansas (on the Ozark Quadrangle map).

- (2) *Boundary Description:*
 - (i) From the crossing of the Missouri Pacific Railroad over Gar Creek, following the railroad tracks eastward to the crossing over Horsehead Creek (on the Hartman Quadrangle map).
 - (ii) From there northward along Horsehead Creek to the merger with Dirty Creek (on the Coal Hill Quadrangle map).
 - (iii) From there generally northwestward along Dirty Creek to Arkansas Highway 352 (where Dirty Creek passes under the highway as a perennial stream—on the Hunt Quadrangle map).
 - (iv) From there along Highway 352 westward to Arkansas Highway 219 (on the Watalula Quadrangle map).
 - (v) Then southward along Highway 219 to Gar Creek (on the Ozark Quadrangle map).
 - (vi) Then southeastward along Gar Creek to the beginning point.

Signed: May 3, 1984.
 W. T. Drake,
Acting Director.
 Approved: May 15, 1984.
 Edward T. Stevenson,
Deputy Assistant Secretary (Operations).
[FR Doc. 84-14352 Filed 5-23-84, 8:45 am]
 BILLING CODE 4910-31-M

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 2610

Payment of Premiums

AGENCY: Pension Benefit Guaranty Corporation.
ACTION: Final rule.

SUMMARY: This amendment reduces the penalty rate for late payment of premiums set forth in the Pension Benefit Guaranty Corporation's Payment of Premiums regulation. The new provision is needed because increased premium rates have resulted in a substantial increase in the penalty charge, which is a percentage of the unpaid premiums. This amendment is intended to reduce the burden previously placed on plans for the late payment of premiums while not creating an incentive to either file late or not file at all.

EFFECTIVE DATE: This regulation is effective on June 29, 1984.

FOR FURTHER INFORMATION CONTACT: Melanie Franco Nussdorf, Special Counsel, Legal Department (210), Pension Benefit Guaranty Corporation, 2020 K Street, NW., Washington, D.C. 20006, (202) 254-6476. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: Title IV of the Employee Retirement Income Security Act of 1974, 29 U.S.C. 1001 *et seq.*, as amended (the "Act"), provides for a comprehensive pension plan insurance program administered by the Pension Benefit Guaranty Corporation ("PBGC"). Under the statutory scheme, covered plans pay annual premiums presently at \$2.60 per participant for single-employer plans and \$1.40 per participant for multiemployer plans, which are kept in two separate funds and are used to help finance the program. The premiums are used to fund benefits guaranteed by the PBGC. If, upon termination of a single-employer plan, the assets of the plan, plus amounts collectible under § 4062 of the Act, are insufficient to fund benefits guaranteed under § 4022 and § 4022B of the Act, the PBGC uses premiums in the single-employer fund to pay these benefits. Similarly, premiums in the multiemployer fund are used to pay benefits guaranteed under section 4022A and section 4022B of the Act.

The PBGC's Payment of Premiums regulation is set forth in 29 CFR Part 2610. This amendment revises § 2610.8 of the Payment of Premiums regulation to reduce the basic late payment penalty charge and to institute a minimum late payment penalty charge. In addition, the amendment clarifies § 2610.9 of the regulation.

The present regulation at § 2610.8 provides an escalating percentage penalty charge on the unpaid premium amount, which begins at 5% for payments under 30 days overdue and reaches 100% after 180 days. This amendment reduces the late payment of premiums penalty charge to the greater of: (1) 5% of the unpaid premiums per month or fraction thereof, up to 100% or (2) the lesser of \$25 or 100% of the unpaid premiums. Thus, a delinquent plan sponsor will be charged at the rate of 100% after 20 months, rather than after 6 months as the present regulation provides.

Since the late payment penalty rate was established, premiums have increased for both singly-employer plans and multiemployer plans (§ 2610.5) and there has been public sentiment to reduce the resulting increased late