

requires that a notice of proposed rulemaking and an opportunity for public comment be given for this rule. Because a notice of proposed rulemaking and opportunities for public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, are inapplicable. Therefore, this regulation is issued in final form. Although there is no formal comment period, public comments on this regulation are welcome on a continuing basis. Comments should be submitted to Frank J. Ruggiero, Office of Exporter Services, Bureau of Export Administration, Department of Commerce, P.O. Box 273, Washington, D.C. 20044.

#### List of Subjects in 15 CFR Parts 746

Embargoes, Exports, Foreign trade, Reporting and recordkeeping requirements.

Accordingly, Part 746 of the Export Administration Regulations (15 CFR Parts 730–774) is amended to read as follows:

1. The authority citation for 15 CFR Part 746 is revised to read as follows:

**Authority:** 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 287c; 22 U.S.C. 6004; E.O. 12854, 58 FR 36587, 3 CFR 1993 Comp., p. 614; E.O. 12918, 59 FR 28205, 3 CFR, 1994 Comp., p. 899; E.O. 12924, 59 FR 43437, 3 CFR, 1994 Comp., p. 917; E.O. 13088, 63 FR 32109, 3 CFR, 1998 Comp., p. 191; E.O. 13121 of April 30, 1999, 64 FR 24021 (May 5, 1999); Notice of August 10, 1999, 64 FR 44101 (August 13, 1999).

#### PART 746—[AMENDED]

2. Section 746.4 is amended by revising paragraph (b)(2)(ii)(G) to read as follows:

##### § 746.4 Libya

\* \* \* \* \*

(b) \* \* \*

(2) \* \* \*

(ii) \* \* \*

(G) Aircraft and vessels (AVS) for vessels only (see § 740.15 (c)(1) of the EAR), and temporary reexports of foreign registered aircraft (see § 740.15 (a)(4) of the EAR).

\* \* \* \* \*

Dated: September 7, 1999.

**Iain S. Baird,**

*Deputy Assistant Secretary for Export Administration.*

[FR Doc. 99–23785 Filed 9–10–99; 8:45 am]

BILLING CODE 3510–33–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 5

#### Delegations of Authority and Organization; Technical Amendment

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

**ACTION:** Final rule; technical amendment.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the regulations for delegations of authority to correct position titles for delegates in the Center for Drug Evaluation and Research (CDER). This action is necessary to ensure the continued accuracy of the regulations.

**EFFECTIVE DATE:** September 13, 1999.

#### FOR FURTHER INFORMATION CONTACT:

Leanne Cusumano, Center for Drug Evaluation and Research (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041, or

Donna G. Page, Division of Management Programs (HFA–340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4816.

**SUPPLEMENTARY INFORMATION:** FDA is correcting its regulations in subpart B of part 5 (21 CFR part 5) in two sections that reflect incorrect position titles for delegates within CDER. In the **Federal Register** of January 17, 1997 (62 FR 2554), FDA amended the regulations for delegations of authority to update titles of CDER delegates and organizational components to reflect organizational restructuring. In two instances, the position titles for the Director and Deputy Director, Office of Generic Drugs (OGD), Office of Pharmaceutical Science (OPS), CDER were inadvertently changed to reflect the Director and Deputy Director, Division of Bioequivalence, OGD, OPS, CDER. Previously, the Director and Deputy Director, OGD, OPS, CDER held those authorities. The Director and Deputy Division Director of Bioequivalence titles should be removed.

#### List of Subjects in 21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 5 is amended as follows:

## PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR part 5 continues to read as follows:

**Authority:** 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261–1282, 3701–3711a; 15 U.S.C. 1451–1461; 21 U.S.C. 41–50, 61–63, 141–149, 321–394, 467f, 679(b), 801–886, 1031–1309; 35 U.S.C. 156; 42 U.S.C. 241, 242, 242a, 242l, 242n 243, 262, 263, 264, 265, 300u–300u–5, 300aa–1; 1395y, 3246b, 4332, 4831(a), 10007–10008; E.O. 11921, 41 FR 24294, 3 CFR, 1977 Comp., p. 124–131; E.O. 12591, 52 FR 13414, 3 CFR, 1988 Comp., p. 220–223.

#### § 5.22 [Amended]

2. Section 5.22 *Certification of true copies and use of Departmental seal* is amended by removing paragraph (a) (13) (viii).

3. Section 5.31 is amended by revising paragraph (f) (3) to read as follows:

#### § 5.31 Petitions under part 10.

(f) \* \* \*

(3) The Director and Deputy Director, Office of Generic Drugs, Office of Pharmaceutical Science, CDER, except for those drug products listed in § 314.440(b) of this chapter, are authorized to issue responses to citizen petitions submitted under § 10.30 of this chapter seeking a determination of the suitability of an abbreviated new drug application for a drug product.

\* \* \* \* \*

4. Section 5.93 is amended by revising paragraph (b) to read as follows:

#### § 5.93 Submission of and effective approval dates for abbreviated new drug applications and certain new drug applications.

\* \* \* \* \*

(b) The Director and Deputy Director, Office of Generic Drugs, Office of Pharmaceutical Science, CDER.

\* \* \* \* \*

Dated: September 7, 1999.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning and Legislation.*

[FR Doc. 99–23683 Filed 9–10–99; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 558

#### New Animal Drugs for Use in Animal Feeds; Nicarbazine and Bambermycins

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

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Hoechst Roussel Vet. The NADA provides for combining approved single ingredient nicarbazin and bambermycins Type A medicated articles to make Type C medicated broiler chicken feeds to be used as an aid in preventing outbreaks of cecal and intestinal forms of coccidiosis, and for increased rate of weight gain and improved feed efficiency.

**EFFECTIVE DATE:** September 13, 1999

**FOR FURTHER INFORMATION CONTACT:** Charles J. Andres, Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-1600.

**SUPPLEMENTARY INFORMATION:** Hoechst Roussel Vet, 30 Independence Blvd., P.O. Box 4915, Warren, NJ 07059, filed NADA 140-339 that provides for combining approved single ingredient Nicarb® (nicarbazin) and Flavomycin® (bambermycins) Type A medicated articles to make Type C medicated broiler chicken feeds containing 113.5 grams per ton (g/t) nicarbazin and 1 to 2 g/t bambermycins. The Type C medicated broiler chicken feeds are used as an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina*, *E. maxima*, *E. necatrix*, and *E. brunetti*) coccidiosis, and for increased rate of weight gain and improved feed efficiency in broiler chickens. The NADA is approved as of August 6, 1999, and the regulations are amended in § 558.95 (21 CFR 558.95) by adding paragraph (d)(5)(iv), and in 21 CFR 558.366 in the table in paragraph

(c) by adding an entry, to reflect the approval. Also, the introductory text of § 558.95(d)(5) is revised to better reflect the combination approvals.

In accordance with the freedom of information provisions of 21 CFR parts 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

This approval is for use of single ingredient Type A medicated articles to make combination drug Type C medicated feeds. One ingredient, nicarbazin, is a Category II drug as defined in 21 CFR 558.3(b)(1)(ii). As provided in 21 CFR 558.4(b), an approved form FDA 1900 is required to make Type C medicated feed from a Category II drug. Under section 512(m) of the act (21 U.S.C. 360b(m)), as amended by the Animal Drug Availability Act of 1996 (Public Law 104-250), medicated feed applications have been replaced by a requirement for feed mill licenses. Therefore, use of Type A medicated articles to make Type C medicated feeds as provided in NADA 140-339 is limited to manufacture in a licensed feed mill.

The agency has determined under 21 CFR 25.33(a)(2) 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.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because

it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

**List of Subjects in 21 CFR Part 558**

Animal drugs, Animal feeds.

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 558 is amended as follows:

**PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS**

1. The authority citation for 21 CFR part 558 continues to read as follows:

**Authority:** 21 U.S.C. 360b, 371.

2. Section 558.95 is amended by revising the introductory text of paragraph (d)(5) and by adding paragraph (d)(5)(iv) to read as follows:

**§ 558.95 Bambermycins.**

\* \* \* \* \*

(d) \* \* \*

(5) Bambermycins may be used in chickens as in paragraph (d)(1) of this section in combination with:

\* \* \* \* \*

(iv) Nicarbazin as in § 558.366.

3. Section 558.366 is amended in the table in paragraph (c) under the entry for "113.5 (0.0125 pct)" by alphabetically adding an item for "Bambermycins 1 to 2" and revising the item for "Lincomycin 2" to read as follows:

**§ 558.366 Nicarbazin.**

\* \* \* \* \*

(c) \* \* \*

Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
* *	* *	* *	* *	* *
113.5 (0.0125 pct)		* * *	* * *	* * *
* *	* *	* *	* *	* *
	Bambermycins 1 to 2	Broiler chickens; aid in preventing outbreaks of cecal ( <i>Eimeria tenella</i> ) and intestinal ( <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. necatrix</i> , and <i>E. brunetti</i> ) coccidiosis, for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; do not use as a treatment for coccidiosis; do not use in flushing mashers; do not feed to laying hens; withdraw 4 days before slaughter. Nicarbazin as provided by 063271.	012799

Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Lincomycin 2 (0.00044 pct)	Broiler chickens; aid in preventing outbreaks of secal ( <i>Eimeria tenella</i> ) and intestinal ( <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. necatrix</i> , and <i>E. brunetti</i> ) coccidiosis; for increased rate of weight gain.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; do not use as a treatment for coccidiosis; do not use in flushing mashers; do not feed to laying hens; withdraw 4 days before slaughter.	060728 063271
*	*	*	*	*

Dated: August 30, 1999.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 99-23665 Filed 9-10-99; 8:45 am]

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## DEPARTMENT OF THE TREASURY

### Bureau of Alcohol, Tobacco and Firearms

#### 27 CFR Part 4

[T.D. ATF-417; Ref. Notice No. 871]

RIN: 1512-AB80

#### Extension for Johannisberg Riesling; Additional Grape Varieties (98R-406P)

**AGENCY:** Bureau of Alcohol, Tobacco and Firearms (ATF), Department of the Treasury.

**ACTION:** Treasury Decision, final rule.

**SUMMARY:** This final rule amends the wine labeling regulations to allow use of the term "Johannisberg Riesling" on American wine labels for an additional seven years. The effect of this amendment allows American wineries additional time to educate consumers regarding the name change and allow for transitional time regarding the labeling, packaging and merchandising of Johannisberg Riesling. Additionally, ATF is adding two new names, Traminette and Aglianico, to the list of prime grape variety names for use in designating American varietal wines.

**EFFECTIVE DATE:** October 1, 1999.

**FOR FURTHER INFORMATION CONTACT:** Ms. Teri Byers, Regulations Division, 650 Massachusetts Avenue, NW, Washington, DC 20226; Telephone (202) 927-8195, or alcohol/tobacco@atfhq.atf.treas.gov.

**SUPPLEMENTARY INFORMATION:**

## Background

### Law and Regulations

Section 105(e) of the Federal Alcohol Administration Act (FAA Act), 27 U.S.C. 205(e), vests broad authority in the Director, as a delegate of the Secretary of the Treasury, to prescribe regulations intended to prevent deception of the consumer, and to provide the consumer with adequate information as to the identity and quality of the product. Regulations which implement the provisions of section 105(e) as they relate to wine are set forth in title 27, Code of Federal Regulations, part 4.

The regulations at § 4.23(b) provide that a grape variety name may be used as the type designation of a grape wine if not less than 75 percent of the wine is derived from grapes of that variety. The wine must be labeled with an appellation of origin. Under § 4.23(d), a bottler may use two or more grape variety names as the type designation of a grape wine if all the wine is made from grapes of the labeled varieties, and the percentage of the wine derived from each grape variety is shown on the label.

#### T.D. ATF-370

In 1996, ATF issued a final rule containing a list of approved prime grape variety names which may be used as the designation for American wines. The purpose of creating a list of prime grape variety names was to help standardize wine label terminology and prevent consumer confusion by reducing the large number of synonyms for grape varieties that were previously used for labeling American wines.

The rule contained two other lists of alternative names that could be used as grape wine designations until January 1, 1997, or January 1, 1999. Finally, the rule also contained a procedure by which interested persons could petition

the Director for the addition of names to the list of prime grape names.

### Johannisberg Riesling

In T.D. ATF-370, ATF announced that the name "Johannisberg Riesling" should no longer be permitted as a grape variety designation on American wines. The true name for this grape variety is simply "Riesling." However, in the United States, wineries had long used the terms "Johannisberg Riesling" and "White Riesling" to distinguish the true Riesling grape from other grapes that were incorrectly designated as "Riesling."

The final rule listed "Riesling" as the prime name for this grape. The term "White Riesling" was listed as a synonym for "Riesling." This term is used internationally as a designation for this wine, and is also the botanical name for this grape.

The final rule placed the name "Johannisberg Riesling" as an alternative name that could be used only to label American wines bottled prior to January 1, 1999. ATF noted that "Johannisberg Riesling" is not the correct name for this grape variety. Furthermore, "Johannisberg" is a German geographic term, and the name of a specific winegrowing region within Germany. Since the final rule authorized use of the name Riesling, standing by itself, as the prime name for wine made from this grape, ATF determined that there was no longer the necessity to distinguish wine made from the true Riesling grape by use of the term "Johannisberg Riesling." Owing to the necessity to prepare new packaging and marketing materials, its use was authorized for wines bottled prior to January 1, 1999.

### Petition

ATF subsequently received a petition from the law firm of Buchman & O'Brien, filed on behalf of trade