

§ 404.1343 When the limits on granting World War II and post-World War II wage credits do not apply.

(b) If you are the surviving spouse or child of a veteran of the World War II period or post-World War II period and you are entitled under the Civil Service Retirement Act of 1930 to a survivor's annuity based on the veteran's active service and—

(1) You give up your right to receive the survivor's annuity;

(2) A benefit under the Civil Service Retirement Act of 1930 based on the veteran's active service was not payable to the veteran; and

(3) Another Federal benefit is not payable to the veteran or his or her survivors except as described in paragraph (c) of this section; or

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Food and Drug Administration

21 CFR Parts 100, 182, and 184

[Docket No. 83N-0211]

GRAS Status of Copper Gluconate, Copper Sulfate, Cuprous Iodide, and Peptonized Copper

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that copper gluconate, copper sulfate, and cuprous iodide are generally recognized as safe (GRAS) as direct human food ingredients. In addition, the agency finds that peptonized copper is not GRAS. The safety of these ingredients has been evaluated under the comprehensive safety review conducted by the agency.

DATES: Effective July 12, 1984. The Director of the Federal Register approves the incorporation by reference of certain publications at 21 CFR 184.1260 effective on July 12, 1984.

FOR FURTHER INFORMATION CONTACT: Robert Leo Martin, Center for Food Safety and Applied Nutrition (formerly Bureau of Foods) (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, D.C. 20204, 202-426-8950.

SUPPLEMENTARY INFORMATION: In the Federal Register of February 1, 1984 (49 FR 4008), FDA published a proposal to affirm that copper gluconate, copper sulfate, and cuprous iodide are GRAS for use as direct human food ingredients and to find that peptonized copper is not GRAS. The proposal was published in accordance with the announced FDA

review of the safety of GRAS and prior-sanctioned food ingredients.

In accordance with § 170.35 (21 CFR 170.35), copies of the scientific literature review and the report of the Select Committee on GRAS Substances (the Select Committee) on copper gluconate, copper sulfate, and cuprous iodide are available for public review in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. Copies of these documents also are available for public purchase from the National Technical Information Service, as announced in the proposal.

In addition to proposing to affirm the GRAS status of copper gluconate, copper sulfate, and cuprous iodide, FDA gave public notice that it was unaware of any prior-sanctioned food ingredient use for these ingredients or for peptonized copper other than the proposed conditions of use. Persons asserting additional or extended use in accordance with approvals granted by the U.S. Department of Agriculture or FDA before September 6, 1958, were given notice to submit proof of those sanctions, so that the safety of any prior-sanctioned uses could be determined. That notice was also an opportunity to have prior-sanctioned uses of copper gluconate, copper sulfate, cuprous iodide, and peptonized copper recognized by issuance of an appropriate regulation under Part 181—Prior-Sanctioned Food Ingredients (21 CFR Part 181) or affirmed as GRAS under Part 184 or 186 (21 CFR Part 184 or 186), as appropriate.

FDA also gave notice that failure to submit proof of an applicable prior sanction in response to the proposal would constitute a waiver of the right to assert that sanction at any future time.

No reports of prior-sanctioned uses for copper gluconate, copper sulfate, cuprous iodide, or peptonized copper were submitted in response to the proposal. Therefore, in accordance with the proposal, any right to assert a prior sanction for use of copper gluconate, copper sulfate, cuprous iodide, or peptonized copper under conditions different from those set forth in this final rule has been waived.

One comment, from a user of copper salts, was received in response to the agency's proposal. The comment was in agreement with FDA's intent to affirm as GRAS copper gluconate, copper sulfate, and cuprous iodide.

The agency acknowledges this comment. Because this comment essentially agrees with FDA, no changes are being made in the final rule as a result of this comment. The agency is therefore issuing the proposed

regulations, with minor editorial changes, as a final rule. FDA also finds, for the reasons set forth in the proposal (49 FR 4011) that peptonized copper is not GRAS.

In the proposal, FDA stated that it would work with the Committee on Food Chemicals Codex of the National Academy of Sciences to develop acceptable specifications for copper sulfate and cuprous iodide used as direct human food ingredients and would incorporate those specifications into the regulations on these substances when they were developed. To date, however, work on the specifications is still incomplete. Until the specifications are developed, copper sulfate and cuprous iodide for direct food uses must comply with the descriptions in 21 CFR 184.1261 and 184.1265, respectively, and be of food-grade purity (21 CFR 184.1(b)(3) and 170.30(h)(1)).

The agency has previously determined under 21 CFR 25.24(d)(6) (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. FDA has not received any new information or comments that would alter its previous determination.

In accordance with the Regulatory Flexibility Act, the agency previously considered the potential effects that this rule would have on small entities, including small businesses. In accordance with section 605(b) of the Regulatory Flexibility Act, the agency has determined that no significant impact on a substantial number of small entities would derive from this action. FDA has not received any new information or comments that would alter its previous determination.

In accordance with Executive Order 12291, FDA has previously analyzed the potential economic effects of this final rule. As announced in the proposal, the agency has determined that the rule is not a major rule as determined by the Order. The agency has not received any new information or comments that would alter its previous determination.

The agency's findings of no major economic impact and no significant impact on a substantial number of small entities, and the evidence supporting these findings, are contained in a threshold assessment which may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

List of Subjects

21 CFR Part 100

Administrative practice and procedure, Food labeling, Foods.

21 CFR Part 182

Generally recognized as safe (GRAS) food ingredients, Spices and flavorings.

21 CFR Part 184

Direct food ingredients, Food ingredients, Generally recognized as safe (GRAS) food ingredients, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Parts 100, 182, and 184 are amended as follows:

PART 100—GENERAL

§ 100.155 [Amended]

1. Part 100 is amended in § 100.155 *Salt and iodized salt* in paragraph (a) by revising "182.5265" to read "184.1265".

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

2. Part 182 is amended:

§ 182.90 [Amended]

a. In § 182.90 *Substances migrating to food from paper and paperboard products* by removing "Copper sulfate" from the list of substances.

b. By revising § 182.5260, to read as follows:

§ 182.5260 Copper gluconate.

(a) *Product.* Copper gluconate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with current good manufacturing practice.

§§ 182.5265, 182.8260, 182.8265 [Removed]

c. By removing § 182.5265 *Cuprous iodide*, § 182.8260 *Copper gluconate*, and § 182.8265 *Cuprous iodide*.

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

3. Part 184 is amended:

a. By adding new § 184.1260, to read as follows:

§ 184.1260 Copper gluconate.

(a) Copper gluconate [cupric gluconate ($\text{CH}_2\text{OH}(\text{CHOH})_4\text{COO})_2\text{Cu}$, CAS Reg. No. 527-09-3] is a substance that occurs as light blue to bluish-green, odorless crystals, or as a fine, light blue powder.

It is prepared by the reaction of gluconic acid solutions with cupric oxide or basic cupric carbonate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 90, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC. 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC. 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter and as a synergist as defined in § 170.3(o)(31) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice. Copper gluconate may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

b. By adding new § 184.1261, to read as follows:

§ 184.1261 Copper sulfate.

(a) Copper sulfate (cupric sulfate, $\text{CuSO}_4 \cdot 5\text{H}_2\text{O}$, CAS Reg. No. 7758-98-7) usually is used in the pentahydrate form. This form occurs as large, deep blue or ultramarine, triclinic crystals; as blue granules, or as a light blue powder. The ingredient is prepared by the reaction of sulfuric acid with cupric oxide or with copper metal.

(b) FDA is developing food-grade specifications for copper sulfate in cooperation with the National Academy of Sciences. In the interim, this ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20)

of this chapter and as a processing aid as defined in § 170.3(o)(24) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice. Copper sulfate may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

c. By adding new § 184.1265, to read as follows:

§ 184.1265 Cuprous iodide.

(a) Cuprous iodide (copper (I) iodide, CuI , CAS Reg. No. 7681-65-4) is a pure white crystalline powder. It is prepared by the reaction of copper sulfate with potassium iodide under slightly acidic conditions.

(b) FDA is developing food-grade specifications for cuprous iodide in cooperation with the National Academy of Sciences. In the interim, this ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(2), the ingredient is used in food only within the following specific limitations:

Category of food	Maximum treatment level in food	Functional use
Table salt	0.01 percent	Source of dietary iodine.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

Effective date. This regulation is effective July 12, 1984.

(Secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348, 371(a)))

Dated: May 25, 1984.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 84-15625 Filed 6-11-84; 9:45 am]
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21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Tylosin

AGENCY: Food and Drug Administration.
ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the

animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed for Golden Sun Feeds, Inc., providing for manufacturing a 40-gram-per-pound tylosin premix. The premix is used to make finished feeds for swine, beef cattle, and chickens.

EFFECTIVE DATE: June 12, 1984.

FOR FURTHER INFORMATION CONTACT:

Benjamin A. Puyot, Center for Veterinary Medicine (formerly Bureau of Veterinary Medicine) (HFV-130), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3410.

SUPPLEMENTARY INFORMATION: Golden Sun Feeds, Inc., 111 South Fifth St., Estherville, IA 51334, is sponsor of a supplement to NADA 97-567 submitted on its behalf by Elanco Products Co. This supplement provides for the manufacture of a 40-gram-per-pound premix subsequently used to make finished feeds for swine, beef cattle, and chickens for use as in 21 CFR 558.625(f)(1) (i) through (vi). The supplement is approved and the regulations are amended to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of Part 20 (21 CFR Part 20) and § 514.11(e)(2)(ii) (21 CFR 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, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

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 558

Animal drugs, Animal feeds.

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 558 is amended in § 558.625 by revising paragraph (b)(17) to read as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

§ 558.625 Tylosin.

(b) * * *
(17) To 021780: 0.8 and 10 grams per pound, paragraph (f)(1)(vi)(a) of this section; 40 grams per pound, paragraph (f)(1) (i) through (vi) of this section.

* * *
Effective date. June 12, 1984.

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

Dated: June 1, 1984.

Marvin A. Norcross,
Acting Associate Director for Scientific Evaluation.

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21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Bacitracin Zinc, Amprolium and Ethopabate

AGENCY: Food and Drug Administration.

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 International Minerals & Chemical Corp., providing for use of bacitracin zinc and amprolium plus ethopabate premixes to manufacture complete chicken feeds used as an aid in the prevention of coccidiosis and for improved feed efficiency.

EFFECTIVE DATE: June 12, 1984.

FOR FURTHER INFORMATION CONTACT:

Lonnie W. Luther, Center for Veterinary Medicine (formerly Bureau of Veterinary Medicine) (HFV-128), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4317.

SUPPLEMENTARY INFORMATION:

International Minerals & Chemical Corp., P.O. Box 207, Terre Haute, IN 47808, filed NADA 114-794 providing for use of premixes containing either 10, 25, 40, or 50 grams of bacitracin (as bacitracin zinc) per pound with a premix containing 25 percent (113.5 grams per pound) amprolium and 8 percent (36.3 grams per pound) ethopabate to manufacture a complete feed containing

4 to 50 grams of bacitracin per ton of feed, 0.0125 percent (113.5 grams per ton) amprolium, and 0.004 percent (36.3 grams per ton) ethopabate for broilers. The medicated feed is used as an aid in the prevention of coccidiosis and for improved feed efficiency. The NADA is approved and the regulations are amended to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of Part 20 (21 CFR Part 20) and § 514.11(e)(2)(ii) (21 CFR 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, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

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 558

Animal drugs, Animal feeds.

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), § 558.58 is amended in the table in paragraph (e)(1), item (iii), in the entry for "Bacitracin 4 to 50" by redesignating the existing text under "Indications for use" as "1." and by adding a new entry and corresponding entries under "Limitations" and "Sponsor", to read as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

§ 558.58 Amprolium and ethopabate.

* * *

(e) * * *

(1) * * *

Amprolium and ethopabate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(iii) Amprolium 113.5 (0.0125%) and ethopabate 36.3 (0.004%).	* * *	* * *	* * *	
	Bacitracin 4 to 50.....	1. * * *	* * *	