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.

Dated: May 13, 1985.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 85-12290 Filed 5-21-85; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Parts 182 and 184

[Docket No. 79N-0162]

GRAS Status of Tannic Acid

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that the use of tannic acid as a direct human food ingredient is generally recognized as safe (GRAS) with specific limitations. The safety of this ingredient has been evaluated under the comprehensive safety review conducted by the agency.

DATES: Effective June 21, 1985. The Director of the Federal Register approves the incorporation by reference of certain publications in 21 CFR 184.1097 effective on June 21, 1985.

FOR FURTHER INFORMATION CONTACT: John W. Gordon, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-426-5487.

SUPPLEMENTARY INFORMATION: In the Federal Register of October 1, 1982 (47 FR 43396), FDA published a proposal to affirm that tannic acid is GRAS for use as a direct human food ingredient. 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, mutagenic evaluation, teratologic evaluation, and report of the Select Committee on GRAS Substances (the Select Committee) on tannic acid 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 tannic acid, FDA gave public notice that it was unaware of any prior-sanctioned food uses for this ingredient other than the proposed conditions of use. Persons asserting additional or extended uses 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 tannic acid 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 tannic acid were submitted in response to the proposal. Therefore, in accordance with that proposal any right to assert a prior sanction for use of tannic acid under conditions different from those set forth in this final rule has been waived.

FDA received one comment in response to the proposal. The comment asked that the sources of tannic acid listed in § 184.1097(a) be expanded to include the natural sources of the ingredient that are included in the U.S. Pharmacopoeia XX, first supplement, and the Fourteenth Report of the Joint Food and Agriculture Organization of the United Nations/World Health Organization (1971). The comment specifically requested that final rule include nutgalls of various sumac species, including *Rhus coriaria* and *R. typhia* from the Mediterranean region and America. The comment also pointed out that tara pods (*Caesalpinia spinosa*) are grown in South America and Africa, not in the eastern Mediterranean region as described in the proposal.

The agency has reviewed the references cited by this comment and finds that the comment is correct regarding the use of *Rhus coriaria* and *R. typhia* as sumac sources of tannic acid. The references cited by the comment also mention *Rhus galabra* as an additional example of a sumac plant that is used as a source of tannic acid. The references also mention *Quercus infectoria Oliver* as an example of the plants of the *Quercus* species that are used as sources of this food ingredient. FDA finds that all of these plants have traditionally been used as botanical sources of food-grade tannic acid. The agency is therefore revising § 184.1097(a) to mention specifically these sources of tannic acid.

The agency also finds that there are no safety issues that would require stipulation of the regions in which tara pods *(Caesalpinia spinosa)* or other plant sources of tannic acid are grown. Accordingly, the agency has modified § 184.1097(a) by deleting the reference to the regions in which the tara pods are grown.

The agency has previously determined pursuant to 21 CFR 25.24(b)(7) (April 26, 1985; 50 FR 16636) 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.

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 (address above).

List of Subjects

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 and under authority delegated to the Commissioner of Food and Drugs, Parts 182 and 184 are amended as follows:

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

1. The authority citation for Part 182 is revised to read as follows:

Authority: Secs. 201(s), 402, 409, 701, 52 Stat. 1046–1047 as amended, 1055–1056 as amended, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 342, 348, 371); 21 CFR 5.10.

§ 182.20 [Amended]

2. Part 182 is amended in § 182.20 *Essential oils, oleoresins (solvent-free), and natural extractives (including distillates)* by removing the entry "Tannic acid."

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

3. The authority citation for Part 184 is revised to read as follows:

Authority: Secs. 201(s), 402, 409, 701, 52 Stat. 1046–1047 as amended, 1055–1056 as amended, 72 Stat. 1784–1788 as amended 21 U.S.C. 321(s), 342, 348, 371); 21 CFR 5.10.

4. Part 184 is amended by adding new § 184.1097, to read as follows:

§ 184.1097 Tannic acid.

(a) Tannic acid (CAS Reg. No. 1401–55–4), or hydrolyzable gallotannin, is a complex polyphenolic organic structure that yields gallic acid and either glucose or quinic acid as hydrolysis products. It is a yellowish-white to light brown substance in the form of an amorphous, bulky powder, glistening scales, or spongy masses. It is also ordorless, or has a faint characteristic odor, and has an astringent taste. Tannic acid is obtained by solvent extraction of nutgalls or excrescences that form on the young twigs of *Quercus infectoria Oliver* and related species of *Quercus*. Tannic acid is also obtained by solvent extraction of the seed pods of Tara (*Caesalpinia spinosa*) or the nutgalls of various sumac species, including *Rhus semialata, R. coriaria, R. galabra*, and *R. typhia*.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 319, 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) (1) In accordance with § 184.1(b)(2), the ingredient is used in food only within the following specific limitations:

Category of food	Maximum level of use in food (as served) (percent)	Functional use
Baked goods and baking mixes, § 170.3(n)(1) of this chapter	0.01	Flavoring agent and adjuvant, § 170.3(o)(12) of this chapter.
Alcoholic beverages, § 170.3(n)(2) of this chapter	0.015	Flavor enhancer, § 170.3(o)(11) of this chapter; flavoring agent and adjuvant, § 170.3(o)(12) of this chapter; processing aid, § 170.3(o)(24) of this chapter.
Nonalcoholic beverages and beverage bases, § 170.3(n)(3) of this chapter and for gelatins, puddings, and fillings, § 170.3(n)(22) of this chapter.	0.005	Flavoring agent and adjuvant, § 170.3(o)(12) of this chapter; pH control agent, § 170.3(o)(23) of this chpater.
Frozen dairy desserts and mixes, § 170.3(n)(20) of this chapter and for soft candy, § 170.3(n)(36) of this chapter.	0.04	Flavoring agent and adjuvant, § 170.3(o)(12) of this chapter
Hard candy and cough drops, §170.3(n)(25) of this chapter.	0.013	Do.
Meat products, § 170.3(n)(29) of this chapter	0.001	Do.

(2) Tannic acid may be used in rendered animal fat in accordance with 9 CFR 318.7.

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

Dated: May 1, 1985.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 85–12286 Filed 5–21–85; 8:45 am]

BILLING CODE 4160–01–M

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21 CFR Parts 182 and 184

[Docket No. 77N–0034]

GRAS Status of Licorice, (Glycyrrhiza), Ammoniated Glycyrrhizin, and Monoammonium Glycyrrhizinate

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that licorice (glycyrrhiza), ammoniated glycyrrhizin, and monoammonium glycyrrhizinate are generally recognized as safe (GRAS), with specific limitations, as flavoring agents, flavor enhancers, and surfactants for use in human food, except when used as a component of sugar substitutes. The safety of these ingredients has been evaluated under the comprehensive safety review conducted by the agency.

DATES: Effective June 21, 1985. The Director of the Federal Register approves the incorporation by reference of certain publications in 21 CFR 184.1408 on June 21, 1985.

FOR FURTHER INFORMATION CONTACT: Damon Larry, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C. Street SW., Washington, DC 20204, 202–426–8950.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 2, 1977 (42 FR 39117), FDA published a proposal to affirm that licorice (glycyrrhiza) and ammoniated glycyrrhizin are GRAS, with specific limitations, for use as direct human food ingredients. In the **Federal Register** of May 15, 1979 (44 FR 28334), FDA proposed that ammoniated glycyrrhizin be affirmed as GRAS for use only as a licorice flavor in specific foods or as a surfactant in nonalcoholic beverages. FDA published the proposals in accordance with its announced review of GRAS and prior-sanctioned food ingredients.

FDA received eight comments on the August 2, 1977 proposal and nine comments on the May 15, 1979 amended proposal. Based upon information submitted in these comments, in the **Federal Register** of December 8, 1983 (48 FR 54983), FDA published a tentative final rule and gave interested persons an opportunity to comment on the following changes:

1. The adoption of a gas chromatographic assay for glycyrrhizin, measured as glycyrrhetic acid, in place of the previously announced spectrophotometric method.

2. The interchangeable use of licorice, licorice extract, ammoniated

glycyrrhizin, and monoammonium glycyrrhizinate in food.

3. The inclusion of additional food uses for these ingredients.

That document tentatively affirmed that licorice (glycyrrhiza), ammoniated glycyrrhizin, and monoammonium glycrrhizinate are GRAS, with specific limitations, for use in human food as flavoring agents, flavor enhancers, and surfactants, except when used as a component of sugar substitutes.

FDA received two comments in response to the tentative final rule. Both comments requested modification of 21 CFR 184.1408(b)(1) to include a high pressure liquid chromatographic (HPLC) method of analysis for glycyrrhizic acid or glycyrrhizic acid salts in licorice (Ref. 1). The comments pointed out that this method was published in 1982 by the Association of Analytical Chemists (AOAC) as an "Official First Action."

FDA stated in the tentative final rule that it would consider adopting this HPLC method when the method was validated and published by the AOAC (48 FR 54984). The agency has now reviewed the method and agrees with the comments that it is appropriate to include the HPLC method in the regulation. However, because the gas chromatographic method listed in the tentative final rule retains its AOAC validation, FDA finds that there is no need to delete that assay method from the regulation. Accordingly, the final regulation on licorice (glycyrrhiza) and ammoniated glycyrrhizin will permit the use of either the gas chromatographic method or the HPLC method for the determination of the glycyrrhizin content of licorice.

No other comments were made on the tentative final rule. The agency is therefore issuing the tentative final rule as a final rule without any additional changes.

The agency has previously determined pursuant to 21 CFR 25.24(b)(7) (April 26, 1985; 50 FR 16636) 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.

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.

Reference

The following information has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m. Monday through Friday.

1. "Changes in Methods," Section 19C., *Journal of the Association of Official Analytical Chemists*, 65:471-472, 1982.

List of Subjects

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 and under authority delegated to the Commissioner of Food and Drugs, Parts 182 and 184 are amended as follows:

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

1. The authority citation for Part 182 continues to read as follows:

Authority: Secs. 201(s), 402, 409, 701, 52 Stat. 1046-1047 as amended, 1055-1056 as amended, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 342, 348, 371); 21 CFR 5.10.

§ 182.10 [Amended]

2. Part 182 is amended in § 182.10 *Spices and other natural seasonings and flavorings* by removing the entries for "Glycyrrhiza" and "Licorice."

§ 182.20 [Amended]

3. Part 182 is amended in § 182.20 *Essential oils, oleoresins (solvent-free), and natural extractives (including distillates)* by removing the entries for "Glycyrrhiza," "Glycyrrhiza, ammoniated," and "Licorice."

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

4. The authority citation for Part 184 continues to read as follows:

Authority: Secs. 201(s), 402, 409, 701, 52 Stat. 1046-1047 as amended, 1055-1056 as amended, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 342, 348, 371); 21 CFR 5.10.

5. Part 184 is amended by adding new § 184.1408, to read as follows:

§ 184.1408 Licorice and licorice derivatives.

(a) (1) Licorice (glycyrrhiza) root is the dried and ground rhizome and root portions of *Glycyrrhiza glabra* or other species of *Glycyrrhiza*. Licorice extract is that portion of the licorice root that is, after maceration, extracted by boiling water. The extract can be further purified by filtration and by treatment with acids and ethyl alcohol. Licorice extract is sold as a liquid, paste ("block"), or spray-dried powder.

(2) Ammoniated glycyrrhizin is prepared from the water extract of licorice root by acid precipitation followed by neutralization with dilute ammonia. Monoammonium glycyrrhizinate ($C_{42}H_{61}O_{16}NH_45H_2O$, CAS Reg. No. 1407-03-0) is prepared from ammoniated glycyrrhizin by solvent extraction and separation techniques.

(b) The ingredients shall meet the following specifications when analyzed:

(1) *Assay.* The glycyrrhizin content of each flavoring ingredient shall be determined by the method in the Official Methods of Analysis of the Association of Official Analytical Chemists, 13th Ed., §§ 19.136-19.140, which is incorporated by reference, or by methods 19.CO1 through 19.CO4 in the *Journal of the Association of Official Analytical Chemists*, 65:471-472 (1982), which are also incorporated by reference. Copies of all of these methods are available from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) *Ash.* Not more than 9.5 percent for licorice, 2.5 percent for ammoniated glycyrrhizin, and 0.5 percent for monoammonium glycyrrhizinate on an anhydrous basis as determined by the method in the Food Chemicals Codex, 3d Ed. (1981), p. 466, 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.

(3) *Acid unsoluble ash.* Not more than 2.5 percent for licorice on an anhydrous basis as determined by the method in the Food Chemicals Codex, 3d Ed. (1981), p. 466, which is incorporated by reference.

(4) *Heavy metals (as Pb).* Not more than 40 parts per million as determined by method II in the Food Chemicals Codex, 3d Ed. (1981), p. 512, which is incorporated by reference.

(5) *Arsenic (As).* Not more than 3 parts per million as determined by the method in the Food Chemicals Codex, 3d Ed. (1981), p. 464, which is incorporated by reference.

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

Category of food	Maximum level in food (percent glycyrrhizin content of food) (as served)	Functional use
Baked foods, §170.3(n)(1) of this chapter	0.05	Flavor enhancer, §170.3(o)(11) of this chapter; flavoring agent, §170.3(o)(12) of this chapter.
Alcoholic beverages, §170.3(n)(2) of this chapter	0.1	Flavor enhancer, §170.3(o)(11) of this chapter; flavoring agent, §170.3(o)(12) of this chapter; surface-active agent, §170.3(o)(29) of this chapter.
Nonalcoholic beverages, §170.3(n)(3) of this chapter	0.15	Do.
Chewing gum, §170.3(n)(6) of this chapter	1.1	Flavor enhancer, §170.3(o)(11) of this chapter; flavoring agent, §170.3(n)(12) of this chapter.
Hard candy, §170.3(n)(25) of this chapter	16.0	Do.
Herbs and seasonings, §170.3(n)(26) of this chapter	0.15	Do.
Plant protein products, §170.3(n)(33) of this chapter	0.15	Do.
Soft candy, §170.3(n)(38) of this chapter	3.1	Do.
Vitamin or mineral dietary supplements	0.5	Do.
All other foods except sugar substitutes, §170.3(n)(42) of this chapter. The ingredient is not permitted to be used as a nonnutritive sweetener in sugar substitutes.	0.1	Do.

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

Dated: April 29, 1985.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 85-12287 Filed 5-21-85; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Parts 510 and 540

Penicillin Antibiotic Drugs for Animal Use; Change of Sponsor

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor of a new animal drug application (NADA) for penicillin G procaine-dihydrostreptomycin sulfate for dry cow intramammary infusion from West Chemical Products, Inc., to West Agro, Inc.

EFFECTIVE DATE: May 22, 1985.

FOR FURTHER INFORMATION CONTACT: David L. Gordon, Center for Veterinary Medicine (HFV-238), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6243.

SUPPLEMENTARY INFORMATION: West Agro, Inc., 11100 N. Congress Ave., Kansas City, MO 64153, has informed FDA of a change in sponsor for NADA 55-028 from West Chemical Products, Inc., 4216 West St., Long Island City, NY 11101. West Chemical Products, Inc., has confirmed the change of sponsor. The NADA covers use of penicillin G procaine-dihydrostreptomycin sulfate for dry cow intramammary infusion. With the sponsor change, West Chemical Products is no longer the sponsor of an approved NADA. In addition, West Agro, Inc., has not been previously added to the list of sponsors in 21 CFR 510.600(c). The regulations are amended to provide for the change of sponsor and the new sponsor listing, and to remove the outdated sponsor listing. Approval of a sponsor change is an administrative change that does not otherwise affect approval of the firm's NADA.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 540

Animal drugs, Antibiotics, penicillin.

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, Parts 510 and 540 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for Part 510 is revised to read as follows:

Authority: Secs. 512, 701(a), 52 Stat. 1055, 82 Stat. 343-351 (21 U.S.C. 360b, 371(a)); 21 CFR 5.10 and 5.83.

2. In § 510.600 by removing the entry for West Chemical Products from paragraph (c) (1) and (2) and by adding a new sponsor entry alphabetically to paragraph (c)(1) and numerically to paragraph (c)(2) to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * *	
West Argo, Inc., 11100 N. Congress Ave., Kansas City, MO 64153	033392
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
033392	West Argo, Inc., 11100 N. Congress Ave., Kansas City, MO 64153.
* * * * *	

PART 540—PENICILLIN ANTIBIOTIC DRUGS FOR ANIMAL USE

3. The authority citation for Part 540 is revised to read as follows:

Authority: Sec. 512, 82 Stat. 343-351 (21 U.S.C. 360b); 21 CFR 5.10 and 5.83.

§ 540.874e [Amended]

4. In § 540.874e *Penicillin G procaine-dihydrostreptomycin sulfate for intramammary infusion (dry cows)* is amended in paragraph (c)(2) by removing the sponsor number "011538" and inserting in its place "033392".