enhancer or sweetener synergist, reported levels of use are too low to produce a distinct licorice flavor. Authorization for these effects, however, was not intended by the proposal.

The proposal's intent was to permit the use of ammoniated glycyrrhizin as a flavor ingredient primarily to impart a licorice flavor to food. This use would be self-limiting, as evidenced by the relatively few foods containing such a flavor. However, use of ammoniated glycyrrhizin as a sweetener, flavor enhancer, or sweetening synergist would not be similarly self-limiting and could result in food use not contemplated by the proposal. Should this occur, it could greatly expand expected consumption of the ingredient, a condition that cannot be supported by existing safety data. Therefore, based upon this new information, FDA concludes that the ammoniated glycyrrhizin provisions of the August 2, 1977 GRAS affirmation proposal need to by amended so that expanded use of the ingredient, beyond those contemplated by this proposal, cannot take place without additional safety data.

The proposed rule would have permitted ammoniated glycyrrhizin to be used as a flavor agent at a maximum level, as served, of 0.4 percent in chewing gum, 0.24 percent in soft candy, and 0.17 percent in "all other food categories," as well as a suface-active agent in all food categories except chewing gum and soft candy. However, after assessing this new information, FDA concludes that ammoniated glycyrrhizin should be GRAS for use only as an agent to produce licorice flavor and as a surface-active agent in only those food categories reported during the National Academy of Sciences/National Research Council survey of food manufacturers. This amended proposal has therefore adopted these changes.

Although FDA is further limiting the technical effect and food categories of use for ammoniated glycyrrhizin in this amended proposal, the agency will evaluate the safety and effectiveness of nonlicorice flavoring uses of this ingredient, if data are submitted showing the actual levels of use of this ingredient in nonlicorice-flavored foods, the functional effect achieved, the foods in which it is used, and evidence of history of such uses in food. The agency solicits these data, which may result in inclusion of such uses in the final regulation, as comments to this amended proposal. Alternatively, any person wishing to use ammoniated glycyrrhizin in food under conditions different from those listed in this proposed amendment may later submit a GRAS affirmation or food additive petition as described in § 170.35 or 171.1 (21 CFR 170.35 or 171.1).

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 the authority delegated to the Commissioner (21 CFR 5.1), the proposal of August 2, 1977 (42 FR 39119) to amend Parts 182 and 184 is amended in proposed § 184.1408 by revising paragraph (b)(3) to read as follows:

§ 184.1408 Licorice.

* * * * *

(b) * * *

(3) The ingredient is used in food in accordance with § 184.1(b)(2) under the following conditions:

Maximum Usage Levels Permitted

Food (as served)	Percent	Function
Baked goods, § 170.3(n)(1) of this chapter	0.01	Flavor agent, § 170.3(o)(12) of this chapter to produce licorice flavor only.
Alcoholic beverages, § 170.3(n)(2) of this chapter	0.006	Do.
Nonalcoholic beverages, § 170.3(n)(3) of this chapter	0.01	Flavor agent, § 170.3(o)(12) of this chapter to produce licorice flavor only.
Do.	0.002	Surface-active agent, § 170.3(o)(29) of this chapter.
Chewing gum, § 170.3(n)(6) of this chapter	0.4	Flavor agent, § 170.3(o)(12) of this chapter to produce licorice flavor only.
Confections and frostings, § 170.3(n)(9) of this chapter	0.06	Do.
Frozen dairy desserts, § 170.3(n)(20) of this chapter	0.01	Do.
Gelatins and puddings, § 170.3(n)(22) of this chapter	0.01	Do.
Hard candy, § 170.3(n)(25) of this chapter	0.13	Do.
Soft candy, § 170.3(n)(38) of this chapter	0.24	Do.

Interested persons may, on or before July 16, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order.

Dated: May 8, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 77N–0034]

[FR Doc. 79–15070 Filed 5–14–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR PARTS 182, 184, and 186]

Cellulose Derivatives; Affirmation of GRAS Status as Direct and Indirect Human Food Ingredients; Extension of Comment Period

AGENCY: Food and Drug Administration.

ACTION: Extension of Comment Period.

SUMMARY: The agency extends the comment period on its proposal to affirm the generally recognized as safe (GRAS) status of cellulose derivatives as direct and indirect human food ingredients. This action is taken in response to a request for extension of the comment period.

DATE: Written comments by June 25, 1979.

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Corbin I. Miles, Bureau of Foods (HFF–335), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, D.C. 20204, 202–472–4750.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 23, 1979 (44 FR 10751), the Food and Drug Administration proposed to affirm the GRAS status of cellulose derivatives as direct and indirect human food ingredients. Interested persons were invited to submit comments on the proposal by April 24, 1979.

On March 19, 1979, a letter was received from the Dow Chemical Co. The firm requested an extension of the comment period for the GRAS

affirmation proposal for cellulose derivatives for an additional 60 days, to June 25, 1979, to allow sufficient time to prepare comments on the proposed rule.

The agency considers the opportunity to comment on GRAS affirmation proposals to be an important part of the GRAS review process. It has decided that an extension of the comment period for this proposal would be appropriate, and that the additional time should be extended to all interested parties.

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 5.1), the comment period for the GRAS affirmation proposal for cellulose derivatives is extended for an additional 60 days.

Accordingly, interested persons may, on or before June 25, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments (preferably four copies and identified with the Hearing Clerk docket number found in brackets in the heading of this document) regarding the proposal. The envelope containing the comments should be prominently marked "Cellulose Derivatives." Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 8, 1979.

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

[Docket No. 78N-0144]
[FR Doc. 79-15074 Filed 5-14-79; 8:45 am]
BILLING CODE 4110-03-M

[21 CFR Parts 182 and 184]

Glycerophosphates; Proposed Affirmation and Deletion of GRAS Status

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administation (FDA) proposes to affirm calcium glycerophosphate as generally recognized as safe (GRAS) as a direct human food ingredient and to delete manganese and postassium glycerophosphates from the GRAS list. The safety of these ingredients and magnesium glycerophosphate has been evaluated under the comprehensive safety review being conducted by the agency.

DATE: Comments on or before July 16, 1979.

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Corbin I. Miles, Bureau of Foods (HFF–335), Food and Drug Adminmistration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, DC 20204, 202–472–4750.

SUPPLEMENTARY INFORMATION: A comprehensive study of human food ingredients classified as generally recognized as safe (GRAS) or subject to a prior sanction is being conducted by FDA. The Commissioner of Food and Drugs has issued several notices and proposed regulations, published in the **Federal Register** of July 26, 1973 (38 FR 20040), initiating this review, under which the safety of calcium, magnesium, manganese, and potassium glycerophosphates has been evaluated. In accordance with the provisions of § 170.35 (21 CFR 170.35), the Commissioner proposes to affirm the GRAS status of calcium glycerophosphate as a direct human food ingredient and to delete manganese and potassium glycerophosphates from the GRAS list.

Glycerophosphates are the salts of glycerophosphoric acid which occurs in three isomeric forms: the β-glycerophosphoric acid and the D(+) and L(−) forms of the α-glycerophosphoric acid. The salts are prepared by neutralizing glycerophosphoric acid with the appropriate metallic hydroxide. Commercial preparations of the glycerophosphates are a mixture of the three isomers.

Calcium glycerophosphate (§ 182.5201 (21 CFR 182.5201)), manganese glycerophosphate (§ 182.5455 (21 CFR 182.5455)), and potassium glycerophosphate (§ 182.5628 (21 CFR 182.5628)) are listed as GRAS for use as nutrients and/or dietary supplements by regulation published in the **Federal Register** of January 31, 1961 (26 FR 938). Calcium glycerophosphate and magnesium glycerophosphate are listed in § 181.29 (21 CFR 181.29) as specific prior-sanctioned food ingredients for use as stabilizers in the manufacture of food-packaging materials. Calcium and magnesium glycerophosphates are also listed in § 175.300(b)(3)(xxxiii) (21 CFR 175.300(b)(3)(xxxiii)) as miscellaneous materials employed in the production of resinous and ploymeric coatings for food-contact use. In addition, magnesium glycerophosphate is listed in § 175.105 (21 CFR 175.105) for use as a component of adhesives.

A representative cross-section of food manufacturers was surveyed to determine the specific foods in which various glycerophosphates are used and the levels of usage. No reports were received indicating that glycerophosphate salts other than calcium glycerophosphate are added to foods. Calcium glycerophosphate is reportedly used in pudding mixes at a level equivalent to 0.12 to 0.85 gram (g) per serving.

Between 1965 and 1973, imports of glycerophosphoric acid and its derivatives (including calcium, magnesium, and manganese salts) ranged from 30,800 to 59,400 pounds per year. No trend in increasing or decreasing usage was apparent. If all of these imports were added directly to foods, the per capita daily consumption would be less than 0.4 milligram (mg). The agency therefore believes that glycerophosphates as direct food ingredients do not contribute significantly to the intake of calcium, manganese, or potassium and that only trace amounts of calcium and magnesium glycerophosphates could migrate to food from packaging material.

Glycerophosphates have been the subject of a search of the scientific literature from 1920 to the present. The criteria used in the search were chosen to discover any articles that considered (1) chemical toxicity, (2) occupational hazards, (3) metabolism, (4) reaction products, (5) degradation products, (6) any reported carcinogenicity, teratogenicity, or mutagenicity, (7) dose response, (8) reproductive effects, (9) histology, (1) embryology, (11) behavioral effects, (12) detection, and (13) processing. A total of 421 abstracts on glycerophosphates were reviewed and 21 particularly pertinent reports from the literature survey have been summarized in a scientific literature review.

The scientific literature review shows, among other studies, the following information as summarized in the report of the Select Committee on GRAS Substances (the Select Committee), chosen by the Life Sciences Research Office of the Federation of American Societies for Experimental Biology:

While several feeding studies have reported the use of glycerophosphates as antirachitic agents, no reports of acute oral toxicity, few feeding studies, and no reports of teratogenicity, mutagenicity, and carcinogenicity testing specifically designed to demonstrate the safety of using glycerophosphates in food have been found by the Select Committee in its search of scientific reference material.

The *in vitro* Hydrolysis of glycerophosphate by cat and dog intestinal enzymes suggested that orally administered glycerophosphates would be largely hydrolyzed to glycerol and phosphate before absorption. Other reports of the Select Committee have considered the health aspects of glycerol and certain phosphates as food ingredients. Oral doses of 0.3 to 1.2 g of calcium glycerophosphate were reported as a medical use to provide calcium and phosphorus dietary supplements.

Anghileri reported on the fate in the rate of the following intravenously administered β-glycerophosphate: ^{51}Cr, ^{64}Cu, ^{56}Mn, ^{140}La, ^{65}Zn, and ^{85}Sr. Most of the radioactivity was accumulated in the liver, kidney, and spleen; the main excretory route was via the urine. All compounds tested had similar patterns of cation distribution and excretion.

The efficacy of calcium glycerophosphate as a dietary calcium supplement to rachitogenic diets was greater than calcium carbonate, dicalcium phosphate, tricalcium phosphate and calcium lactate when fed to weanling female mice. The α- and β-glycerophosphates of sodium, calcium and magnesium were comparable to monocalcium phosphate as antirachitic agents in rats. The subcutaneous injection of 0.1 to 0.5 g of potassium glycerophosphate into guinea pigs (estimated dose of 0.1 to 0.5 g per kg body weight) resulted in an increase in blood glycerophosphatase activity within 30 minutes.

The addition of calcium glycerophosphate (50 mg per kg) to a high cholesterol diet (0.5 g per kg per day) resulted in an earlier onset of hypercholesterolemia and higher aortic cholesterol levels in experimental than in control rabbits receiving cholesterol to produce atherosclerosis. The addition of glycerin to the high cholesterol diet produced similar results. In another study involving rabbits fed a high cholesterol (0.5 g per kg body weight per day) diet, the addition of calcium glycerophosphate (0.1 g per kg body weight per day) resulted in a higher serum level of esterified cholesterol but no effect on free cholesterol in blood.

In a five-month feeding study of a mixture of α- and β-isomers of calcium glycerophosphate (200 mg per kg), treated rabbits had a slightly increased blood cholesterol level, a decreased blood protein-bound cholesterol level, and an increase in the deposition of total lipids and cholesterol in liver, lung and kidney tissues. No atherosclerotic changes were noted in blood vessels, although changes in other organs suggested experimental atherosclerosis to the author.

Calcium glycerophosphate (50 mg per kg per day) was reported to decrease the respiration rate in rabbit brain, liver and heart muscle after a five-month feeding period with or without the addition of cholesterol to the diet. Cera and Bellini reported that the absorption of neutral fats in rats is enhanced by the addition of sodium glycerophosphate to the fat.

The only reported study concerned with the effects of glycerophosphate on reproduction and/or teratology is that of Landauer and Sopher. Using fertilized chicken eggs, they reported that sodium DL-α-glycerophosphates inhibited the teratogenic effects of 3-acetylpyridine and 6-aminoni-cotinamide, but potentiated the teratogenic effects of acetazolamide and insulin.

Bowen reported that the feeding of 1 percent calcium β-glycerophosphate (a 75:25 mixture of the β-isomer and α-isomers) in a cariogenic diet to monkeys for 30 months resulted in a marked decrease in the incidence of caries. The effectiveness of calcium and sodium α- or β-glycerophosphate as an anticaries agent in rats fed a cariogenic diet was reported by Regolati and Hotz. In this study calcium glycerophosphate at a level of 0.6 percent phosphorus added to the diet caused reduced feed and water intake and retarded growth in weanling rats. The daily intake of calcium glycerophosphate tetrahydrate was about 3 g per kg body weight. Federov reported that calcium glycerophosphate was an active anticaries toothpaste component when tested in rats fed a cariogenic diet.

The intravenous administration of sodium β-glycerophosphate to rabbits with fractured right radii resulted in accelerated healing and larger callouses as compared to control animals. These authors reported that administration of the following doses did not elicit any adverse effect: the intravenous administration of 100 mg (50 per kg body weight) into a rabbit daily for 55 days, and 10 daily intravenous injections of 10 g to a 17 kg dog. However, the intrapertioneal administration of 1.5 to 3 g per kg for two to five days to rabbits was fatal.

In a review of some of the general pharmacological effects of sodium glycerophosphate, Velazquez noted its uterine spasmolytic and respiratory stimulatory properties. Aragon also demonstrated the spasmolytic action of sodium-β-glycerophosphate on uterine smooth muscle. A hypoglycemic effect of subcutaneously injected sodium-β-glycerophosphate in rabbits was reported by Fernandez and Aguilar. The mechanism the authors proposed was that of insulin reinforcement attributable to the phosphoric acid moiety as an activator of glycolysis.

The simultaneous administration of sodium glycerophosphate with aureomycin to rats and guinea pigs resulted in a two to threefold increase in serum levels of the drug when compared to controls. Citric acid, trisodium citrate, malic acid, tartaric acid, tricarballylic acid, monosodium phosphate, malonic acid, pyruvic acid, and lactic acid produced larger increases, but calcium glycerophosphate did not produce an increase. The "Lamson glucose effect" (intraperitoneal injection of certain solutions into an animal just awakening from barbiturate-induced sleep causes the animal to return to sleep) also was induced with β-glycerophosphate in guinea pigs. Sodium-β-glycerophosphate, intravenously administered, was reported to enhance the hypertensive effects of epinephrine; similar doses of sodium-α-glycerophosphate did not.

Qualified scientists of the Select Committee have carefully evaluated all of the available safety information on glycerophosphate salts. In the Select Committee's opinion,

The glycerophosphate salts that are considered to be GRAS could provide absorbable sources of glycerol, phosphate, and their respective cations. However, glycerophosphates are not now widely used in foods. The Select Committee believes that the the level of consumer exposure is very low and that use under limitations as a nutrient or dietary supplement will not present a hazard to the public. In previous evaluations of glycerol and certain phosphates no evidence was found of a hazard to the public from the hyrolysis products of the glycerophosphates.

The Select Committee concludes that there is no evidence in the available information on calcium glycerophosphate, potassium glycerophosphate, and manganese glycerophosphate that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public when they are used as nutrient supplements or as they might reasonably be expected to be so used in the future. There is no evidence in the available information on calcium glycerophosphate and magnesium glycerophosphate that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public when they are used in food packaging materials as now practiced or as they might be expected to be used for such purposes in the future. Based upon his own evaluation of all available information on the

calcium, magnesium, manganese, and potassium salts of glycerophosphoric acid, the Commissioner agrees with this conclusion and therefore finds that no change in the present GRAS status of calcium glycerophosphate is justified. Because no information was submitted on current food uses for manganese and potassium glycerophosphates in response to the survey of food manufacturers, the Commissioner concludes that insufficient data and information are available to affirm the GRAS status of these ingredients. The Commissioner proposes, therefore, to delete manganese and potassium glycerophosphate as GRAS direct human food ingredients unless information is provided that includes human food uses (levels of addition, intended technical effects, and food to which the substance is added) of both ingredients. This information should be submitted as comments on this proposal during the comment period.

Copies of the scientific literature review of glycerophosphates, and the report of the Select Committee are available for review at the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, and may be purchased from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161, as follows:

Title and order number	Price code	Price [1]
Glycerophosphates: scientific literature review (PB–228–543/AS)	A04	$5.25
Glycerophosphates: Select Committee report (PB–265–506/AS)	A02	4.00

[1] Price subject to change.

The prior-sanctioned use of calcium or magnesium glycerophosphate as a stabilizer in packaging materials is not affected by this proposal. This proposal also does not affect the present use of the glycerophosphate salts for pet food or animal feed.

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 (21 CFR 5.1), it is proposed that Parts 182 and 184 be amended as follows:

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

§§ 182.5201, 182.5455, 182.5628 [Deleted]

1. By deleting § 182.5201 *Calcium glycerophosphate,* § 182.5455 *Manganese glycerophosphate,* and § 182.5628 *Potassium glycerophosphate.*

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

2. In Part 184 by adding new § 184.1201 to read as follows:

§ 184.1201 Calcium glycerophosphate.

(a) Calcium glycerophosphate ($C_3H_7CaO_6P$, CAS Reg. No. 27214–00–2) is a fine, white, odorless, almost tasteless, slightly hydroscopic powder. It is prepared by neutralizing glycerophosphoric acid with calcium hydroxide or calcium carbonate. The commercial product is a mixture of calcium β– and D and L–α–glycerophosphates.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 2d Ed. (1972), which is incorporated by reference.[1]

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

(d) The ingredient is used in food at levels not to exceed good manufacturing practice in accordance with § 184.1(b)(1). Current good manufacturing practice results in a maximum levels, as served, of 0.4 percent for gelatins, puddings, and fillings as defined in § 170.3(n)(22) of this chapter.

The Commissioner hereby gives notice that he is unaware of any prior sanction for the use of these ingredients in food under conditions different from those proposed herein or those listed in Part 181 (21 CFR Part 181). Any person who intends to assert or rely on such a sanction shall submit proof of its existence in response to this proposal. The regulations proposed above will constitute a determination that excluded uses would result in adulteration of the food in violation of section 402 of the act, and the failure of any person to come forward with proof of such an applicable prior sanction in response to this proposal constitutes a waiver of the right to assert or rely on the sanction at any later time. This notice also constitutes a proposal to establish a regulation under Part 181 incorporating the same provisions, if such a regulation is determined to be appropriate as a result of submission of proof of such an applicable prior sanction in response to this proposal.

Interested persons may, on or before July 16, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order.

Dated: May 8, 1979.

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

[Docket No. 78–0335]
[FR Doc. 79–15073 Filed 5–14–79; 8:45 am]
BILLING CODE 4110–03–M

[1] Copies may be obtained from the National Academy of Sciences, 2101 Constitution Ave. NW., Washington, DC 20037.

DEPARTMENT OF DEFENSE

Office of the Secretary

[32 CFR Part 214]

Environmental Effects in the United States of DoD Actions, DoD Directive 6050.[1]

AGENCY: Office of the Secretary of Defense.

ACTION: Proposed rule.

SUMMARY: This rule establishes Department of Defense (DoD) policies and procedures to supplement the Council on Environmental Quality (CEQ) Regulations For Implementing the Procedural Provisions of the National Environmental Policy Act, November 29, 1978 (40 CFR Parts 1500–1508). The CEQ regulations provide that Federal agencies shall adopt implementing procedures by July 30, 1979. This rule provides implementing procedures and guidance to the DoD components and assigns responsibilities as required by the CEQ regulation.

DATES: Comments must be received on or before June 14, 1979.

ADDRESSES: Office of the Deputy Assistance Secretary of Defense (Energy, Environment and Safety), The Pentagon, Room 3D 823, Washington, D.C. 20301.

FOR FURTHER INFORMATION CONTACT: Colonel C. D. Sadler, USA, Telephone: 695–0221.

[1] Copies may be obtained, if needed, from the U.S. Naval Publications and Forms Center, 5801 Tabor Avenue, Philadelphia, PA. 19120 Attention: Code 301.