

21 CFR Part 184

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

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

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 182 and 184 are amended as follows:

§ 182.5458 [Removed]

1. Part 182 is amended by removing § 182.5458 *Manganese hypophosphite*.

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

2. Part 184 is amended by adding a new § 184.1764 to read as follows:

§ 184.1764 Sodium hypophosphite.

(a) Sodium hypophosphite (NaH_2PO_2 , CAS Reg. No. 7681-53-0) is a white, odorless, deliquescent granular powder with a saline taste. It is also prepared as colorless, pearly crystalline plates. It is soluble in water, alcohol, and glycerol. It is prepared by neutralization of hypophosphorous acid or by direct aqueous alkaline hydrolysis of white phosphorus.

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

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitations 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 an emulsifier or stabilizer, as defined in §§ 170.3(o)(8) and 170.3(o)(28) of this chapter.

(2) The ingredient is used in cod-liver oil emulsions at levels not to exceed current good manufacturing practice.

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

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

Effective date. This regulation is effective September 30, 1982.

Dated: August 10, 1982.

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

[FR Doc. 82-23701 Filed 8-30-82; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Parts 182 and 184

[Docket No. 78N-0015]

GRAS Status of Inositol

AGENCY: Food and Drug Administration.

ACTION: Final rule.

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

EFFECTIVE DATE: September 30, 1982.

FOR FURTHER INFORMATION CONTACT: John W. Gordon, Bureau of Foods (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-426-5487.

SUPPLEMENTARY INFORMATION: In the Federal Register of May 23, 1978 (43 FR 22056), FDA published a proposal to affirm that inositol 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 on inositol, data on a mutagenic evaluation, and the report of the Select Committee on GRAS Substances (the Select Committee) on inositol 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 have also been made 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 inositol, FDA gave public notice that it was unaware of any prior-sanctioned food ingredient uses for the substance, other than for 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 prior-sanctioned uses could be determined. That notice was also an opportunity to

have prior-sanctioned uses of inositol 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 Parts 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 the sanction at any future time.

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

No comments were received in response to the proposal. Inositol is listed as a GRAS substance for dietary supplement use and nutrient use in §§ 182.5370 and 182.8370 (21 CFR 182.5370 and 21 CFR 182.8370) respectively, as described in the Federal Register publication of September 5, 1980 (45 FR 58837). That notice reorganized Part 182 to establish separate listings for "Dietary Supplements" and "Nutrients." Although there is no direct evidence of a dietary requirement for inositol in healthy adult humans with a mixed and varied diet, it is required by section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) as a required nutrient in infant formula that is not milk based at a minimum level of 4.0 milligrams per 100 kilocalories. FDA is reviewing all nutrient levels in infant formulas under a contract with the American Academy of Pediatrics. Any necessary modifications in the nutrient level of inositol in infant formula will be proposed by a separate rulemaking under section 412 of the act. As described in the proposal, inositol is also used in certain special dietary foods.

Therefore, FDA is removing inositol from § 182.8370 and affirming it as GRAS for use as a nutrient in infant formulas and special dietary foods. The agency is not taking any action on dietary supplement uses of inositol because there is inadequate information regarding these uses.

FDA has modified this final rule to reflect publication of specifications for inositol in the new Food Chemicals Codex, 3d edition. No differences exist between the specifications in the 2d edition, as referenced in the proposal, and those adopted in the 3d edition.

The format of the final regulation is different from that in the proposal and

in previous GRAS affirmation regulations. FDA has modified paragraph (c) of § 184.1370 to make clear that the agency's GRAS affirmation determination is based upon current good manufacturing practice conditions of use, including both the technical effect and food categories listed. This change has no substantive effect but is made merely for clarity.

The agency has 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. Therefore, neither an environmental assessment nor an environmental impact statement is required.

The requirement for a regulatory flexibility analysis under the Regulatory Flexibility Act does not apply to this final rule because the proposed rule was issued prior to January 1, 1981, and therefore exempt.

In accordance with Executive Order 12291, FDA has carefully analyzed the economic effects of this rule, and the agency has determined that the rule is not a major rule as defined by that Order.

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.

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. 301(s), 348, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Parts 182 and 184 are amended as follows:

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

§ 182.8370 [Removed]

1. In Part 182 by removing § 182.8379 *Inositol*.

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

2. In Part 184 by adding new § 184.1370 to read as follows:

§ 184.1370 *Inositol*.

(a) *Inositol*, or *myo-inositol* ($C_6H_{12}O_6$, CAS Reg. No. 87-89-8), is *cis-1,2,3,5-trans-4,6-cyclohexanhexol*. It occurs naturally and is prepared from an

aqueous (0.2 percent sulfur dioxide) extract of corn kernels by precipitation and hydrolysis of crude phytate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 150, 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 limitations 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.

(2) The ingredient is used in special dietary foods as defined in Part 105 of this chapter at levels not to exceed current good manufacturing practice. It may also be used in infant formula in accordance with section 412(g) of 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 by this section do not exist or have been waived.

Effective date. This regulation shall be effective September 30, 1982.

(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 August 10, 1982.

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

Note.—Incorporation by reference was approved by the Director of the Office of the Federal Register on June 4, 1982, and is on file at the Office of the Federal Register.

[FR Doc. 82-23718 Filed 6-30-82; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 202

Prescription Drug Advertising

CFR Correction

In Title 21, Code of Federal Regulations, revised as of April 1, 1982, in Part 202, § 202.1, appearing on page 58, paragraphs (e)(6) (ii) and (vii) read incorrectly. These two paragraphs should read as follows:

(e) * * *

(6) * * *

(ii) Contains a drug comparison that represents or suggests that a drug is

safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience.

* * * * *

(vii) Contains favorable data or conclusions from nonclinical studies of a drug, such as in laboratory animals or in vitro, in a way that suggests they have clinical significance when in fact no such clinical significance has been demonstrated.

BILLING CODE 1505-01-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of Assistant Secretary for Housing—Federal Housing Commissioner

24 CFR Part 201

[Docket No. R-82-1022]

Mortgage Insurance Loans; Changes in Interest Rates

AGENCY: Department of Housing and Urban Development.

ACTION: Final rule.

SUMMARY: This change in the regulations decreases the HUD/FHA maximum allowable finance charge on Title I mobile home loans, property improvement loans, and combination and mobile home lot loans as well as historic preservation loans. This action by HUD is designed to bring the maximum interest rate and financing charges on HUD/FHA-insured loans into line with market rates and help assure an adequate supply of and demand for FHA financing.

EFFECTIVE DATE: August 31, 1982.

FOR FURTHER INFORMATION CONTACT: John L. Brady, Director, Office of Title I Insured Loans, Office of Single Family Housing, Department of Housing and Urban Development, 451 7th Street SW., Washington, D.C. 20410 (202-755-6680).

SUPPLEMENTARY INFORMATION: The following miscellaneous amendments have been made to this chapter to decrease the maximum interest rate which may be charged on loans insured by this Department. Maximum finance charges on property improvement loans have been lowered from 18.50 percent to 17.50 percent, the finance charge on mobile home loans lowered from 17.50 percent to 16.50 percent, and the finance charge on combination loans for the purchase of a mobile home and a

developed or undeveloped lot has been lowered from 17.00 percent to 16.00 percent. The maximum charge on historic preservation loans has been lowered from 18.50 to 17.50 percent.

The Secretary has determined that such changes are immediately necessary to meet the needs of the market and to prevent speculation in anticipation of a change, in accordance with his authority contained in 12 U.S.C. 1709-1, as amended. The Secretary has, therefore, determined that advance notice and public comment procedures are unnecessary and that good cause exists for making this amendment effective immediately.

This is a procedural and administrative determination as set forth in the statutes and as such does not require a determination of environmental applicability.

List of Subjects in 24 CFR Part 201

Health facilities, Historic Preservation, Home improvement, Mobile homes, Manufactured homes and lots.

Accordingly, Chapter II is amended as follows:

PART 201—PROPERTY IMPROVEMENT AND MOBILE HOME LOANS

Subpart A—Eligibility Requirements—Property Improvement Loans

1. Section 201.4(a) is revised to read as follows:

§ 201.4 Financing charges.

(a) *Maximum financing charges.* The maximum permissible financing charge exclusive of fees and charges as provided by paragraph (b) of this section which may be directly or indirectly paid to, or collected by, the insured in connection with the loan transaction, shall not exceed 17.50 percent annual rate. No points or discounts of any kind may be assessed or collected in connection with the loan transaction. Finance charges for individual loans shall be made in accordance with tables of calculation issued by the Commissioner.

* * *

1. Section 201.540(a) is revised to read as follows:

§ 201.540 Financing charges.

(a) *Maximum financing charges.* The maximum permissible financing charge which may be directly or indirectly paid to, or collected by, the insured in connection with the loan transaction, shall not exceed 16.50 percent simple interest per annum. No points or discounts of any kind may be assessed

or collected in connection with the loan transaction, except that a one percent origination fee may be collected from the borrower. If assessed, this fee must be included in the finance charge. Finance charges for individual loans shall be made in accordance with tables of calculation issued by the Commissioner.

* * *

2. Section 201.1511(a)(1) is revised to read as follows:

§ 201.1511 Financing charges.

(a) *Maximum financing charges.*

* * *

(1) 16.00 percent per annum.

* * *

4. Section 201.1625(a) is revised to read as follows:

§ 201.1625 Financing charges.

(a) *Maximum financing charges.* The maximum permissible financing charge, exclusive of fees and charges as provided by paragraph (b) of this section, which may be directly or indirectly paid to, or collected by, the insured in connection with the loan transaction, shall not exceed an 17.50 percent annual rate. No points or discounts of any kind may be assessed or collected in connection with the loan transaction. Finance charges for individual loans shall be made in accordance with tables of calculation issued by the Commissioner.

* * *

(Sec. 3(a), 82 Stat. 113; 12 USC 1709-1; Section 7 of the Department of Housing and Urban Development Act, 42 USC 3534(d))

Dated: August 23, 1982.

Philip Abrams,

General Deputy Assistant Secretary for Housing, Deputy Federal Housing Commissioner.

[FR Doc. 82-23828 Filed 8-30-82; 8:45 am]

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Office of Assistant Secretary for Housing—Federal Housing Commissioner

24 CFR Parts 203, 205, 207, 213, 220, 221, 232, 234, 235, 236, 241, 242, and 244

[Docket No. R-82-1021]

Mortgage Insurance Loans; Changes in Interest Rates

AGENCY: Department of Housing and Urban Development.

ACTION: Final rule.

SUMMARY: This change in the regulations decreases the HUD/FHA interest rates on insured loans. This

action by HUD is designed to bring the maximum interest rates into line with other competitive market rates and help assure an adequate supply of and demand for FHA financing.

EFFECTIVE DATE: August 24, 1982.

FOR FURTHER INFORMATION CONTACT:

John N. Dickie, Director, Financial Analysis Division, Office of Financial Management, Department of Housing and Urban Development, 451 7th Street, SW., Washington, D.C. 20410 (202-426-4667).

SUPPLEMENTARY INFORMATION: The following amendments have been made to this chapter to decrease the maximum interest rate which may be charged on loans by this Department. The maximum interest rate on HUD/FHA insured home mortgage insurance programs has been lowered from 15.00 percent to 14.00 percent for level payment (including operative builder) and graduated payment home loan programs (GPM). For insured multifamily project mortgage loan programs, the maximum interest rate has been lowered from 16.00 percent to 15.00 percent. The maximum interest rate for multifamily construction and Title X land development loans has been lowered from 17.00 percent to 16.00 percent.

The Secretary has determined that such changes are immediately necessary to meet the needs of the market and to prevent speculation in anticipation of a change, in accordance with his authority contained in 12 U.S.C. 1709-1, as amended. The Secretary has, therefore, determined that advance notice and public comment procedures are unnecessary and that good cause exists for making this amendment effective immediately.

This is a procedural and administrative determination as set forth in the statutes and as such does not require a determination of environmental applicability.

List of Subjects in 24 CFR Parts 203, 205, 207, 213, 220, 221, 232, 234, 235, 236, 241, 244, and 245

Mortgage insurance.

Accordingly, Chapter II is amended as follows:

PART 203—MUTUAL MORTGAGE INSURANCE AND REHABILITATION LOANS

1. Section 203.20 paragraph (a) is revised to read as follows:

§ 203.20 Maximum interest rate.

(a) The mortgage shall bear interest at the rate agreed upon by the mortgagee and the mortgagor, which rate shall not