DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 282

[Docket No. RM79-14]

Order of the Director, OPPR of Publication of Incremental Pricing Acquisition Cost Thresholds Under Title II of the NGPA

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Order Prescribing Incremental Pricing Thresholds.

SUMMARY: The Director of the Office of Pipeline and Producer Regulation is issuing the incremental pricing acquisition cost thresholds prescribed by Title II of the Natural Gas Policy Act and 18 CFR 282.304. The Act requires the Commission to compute and publish the threshold prices before the beginning of each month for which the figures apply. Any cost of natural gas above the applicable threshold is considered to be an incremental gas cost subject to incremental pricing surcharging.

EFFECTIVE DATE: October 1, 1985.

FOR FURTHER INFORMATION CONTACT: Kenneth A. Williams, Federal Energy Regulatory Commission, 825 N. Capitol Street NE, Washington, DC 20426, (202) 357-8500.

Order of the Director, OPPR

Publication of Prescribed Incremental Pricing Acquisition Cost Threshold of the NGPA of 1978; Docket No. RM79-14.

Issued: September 23, 1985.

Section 203 of the NGPA requires that the Commission compute and make available incremental pricing acquisition cost threshold prices prescribed in Title II before the beginning of any month for which such figures apply.

Pursuant to that mandate and pursuant to § 375.307(1) of the Commission's regulations, delegating the publication of such prices to the Director of the Office of Pipeline and Producer Regulation, the incremental pricing acquisition cost threshold prices for the month of October 1985 is issued by the publication of a price table for the applicable month. The incremental pricing acquisition cost threshold prices for months prior to October 1985 are found in the tables in § 282.304

List of Subjects in 18 CFR Part 282

Natural gas.

Kenneth A. Williams,

Director, Office of Pipeline and Producer Regulation.

TABLE I.—INCREMENTAL PRICING ACQUISITION COST THRESHOLD PRICES

[Calender year 1984]

	Jan.	Feb.	Mar.	Apr.	May	June	July	Aug.	Sept.	Oct.	Nov.	Dec.
Incremental pricing threshold	$2.283	$2.291	$2.299	$2.307	$2.315	$2.323	$2.331	$2.338	$2.345	$2.352	$2.359	$2.366
NGPA section 102 threshold	3.585	3.609	3.632	3.656	3.680	3.705	3.730	3.752	3.774	3.797	3.821	3.845
NGPA section 109 threshold	2.359	2.367	2.375	2.383	2.391	2.399	2.407	2.414	2.421	2.428	2.436	2.444
130 pct of No. 2 fuel oil in New York City threshold	7.730	7.570	7.570	8.550	8.590	7.670	7.930	7.740	7.650	7.230	7.040	7.290

[Calender year 1985]

	Jan.	Feb.	Mar.	Apr.	May	June	July	Aug.	Sept.	Oct.	Nov.	Dec.
Incremental pricing	$2.373	$2.378	$2.383	$2.388	$2.399	$2.410	$2.421	$2.427	$2.433	$2.439		
NGPA section 102 threshold	3.869	3.890	3.911	3.932	3.962	3.992	4.022	4.045	4.068	4.091		
NGPA section 109 threshold	2.452	2.457	2.462	2.467	2.478	2.489	2.500	2.506	2.512	2.518		
130 pct of No. 2 fuel oil in New York City threshold	7.170	7.310	7.090	6.920	7.210	7.120	7.400	7.000	6.520	6.630		

[FR Doc. 85-22973 Filed 9-24-85; 8:45 am]

BILLING CODE 6717-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 184

[Docket No. 82N-0393]

Gras Status of Sodium Metasilicate and Sodium Zinc Metasilicate

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that the use of sodium metasilicate as a direct human food ingredient is generally recognized as safe (GRAS). In addition, FDA is not affirming that the use of sodium zinc metasilicate as a food ingredient is GRAS because of the absence of safety information. The safety of these ingredients has been evaluated under the comprehensive safety review conducted by the agency.

EFFECTIVE DATE: October 25, 1985.

FOR FURTHER INFORMATION CONTACT: Hortense S. Macon, 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 April 26, 1983 (48 FR 18831), FDA published a proposal to affirm that sodium metasilicate is GRAS for use as a direct human food ingredient and not to affirm sodium zinc metasilicate as GRAS. FDA published this proposal in accordance with its announced review of GRAS and prior-sanctioned food ingredients.

In accordance with § 170.35 (21 CFR 170.35), copies of the scientific literature review on sodium metasilicate and sodium zinc metasilicate and the report of the Select Committee on GRAS Substances (the Select Committee) on these ingredients have been made available for public review at 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 sodium metasilicate, FDA gave public notice that it was unaware of any prior-sanctioned food uses for these ingredients 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 the prior-sanctioned uses could be determined.

That notice was also an opportunity to have prior-sanctioned uses of sodium metasilicate or sodium zinc metasilicate 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 sodium metasilicate or sodium zinc metasilicate were submitted in response to the proposal. However, a comment on the proposal asserted that FDA does not have the authority to waive proof sanctions.

As discussed in the **Federal Register** documents published July 26, 1973 (38 FR 20041, 20042) and December 7, 1976 (41 FR 53600, 53603), FDA does not have a comprehensive list of all prior sanctions. The agency has found it necessary for the proper functioning of its safety review of GRAS and prior-sanctioned substances to require that persons who hold a prior sanction for a particular ingredient inform FDA of that prior sanction at the time the agency proposes a regulation that might be inconsisent with the prior-sanctioned use (41 FR 53603). Thus, the only occasion on which a person must come forward to make known the existence of a prior sanction is when FDA is proposing to limit the use of the ingredient, and the limitations, if imposed, would foreclose the prior-sanctioned use (41 FR 53603). FDA believes that, in this circumstance, it is appropriate to place the burden of coming forward on the person who intends to rely on the prior sanction (41 FR 53603).

The comment also contended that the requirement that anyone who holds a prior sanction must submit proof of that sanction to FDA or face waiving that sanction is unfair to small businesses that rely upon agency opinion letters and that are unfamiliar with FDA's regulations.

The agency disagrees with the comment that this practice is unfair to small businesses. All food manufacturers, to assure that their products are safe for the consuming public and to avoid legal sanctions for noncompliance, must be aware of any limits that FDA has imposed on the use of food ingredients. Congress has determined that the filing of documents with the Office of the Federal Register and the publication of those documents in the **Federal Register** provides adequate notice to the public, including both large and small businesses, of the actions of a Federal agency. See 5 U.S.C. 553 and 44 U.S.C. 1507.

FDA also believes that it would be unfair to both small and large firms not to have the regulations reflect all authorized food uses for each ingredient. If a prior-sanctioned use is safe, the agency believes all businesses should be able to rely upon it.

FDA, therefore, disagrees with the assertions made by this comment and finds that the procedure adopted for waiver of prior sanctions is lawful and is not unfair to small or large food manufacturers.

Thus, because no reports of prior sanctions were submitted in response to the proposal, any right to assert a prior sanction for use of these ingredients 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 was from a manufacturer of sodium metasilicate, who raised several issues. One issue, discussed above, was that FDA does not have the authority to waive prior sanctions. Summaries of the other issues raised by this comment and the agency's responses follow:

1. The comment requested that the final rule be amended to affirm the GRAS status of sodium metasilicate for use in the washing and lye peeling of fruits, vegetables, and nuts; for treating bottled or canned water; and for use as a boiler water additive.

The agency has reviewed this request to affirm as GRAS these additional food uses of sodium metasilicate. FDA finds that the safety data evaluated by the Select Committee and the agency are adequate to permit affirmation of the GRAS status of sodium metasilicate for use in the washing and lye peeling of fruits, vegetables, and nuts, when used in accordance with 21 CFR 173.315; and for use in canned and bottled water, when its use is not inconsistent with the bottled water standard of quality in 21 CFR 103.35. The agency is therefore affirming these uses as GRAS. However, the use of sodium metasilicate as a boiler water additive is already authorized under an existing food additive regualtion (21 CFR 173.310). The agency concludes that it is unnecessary and would be redundant to affirm this use as GRAS.

2. The comment also requested that sodium metasilicate be affirmed as GRAS for use in animal feed and pet food.

The agency is not affirming the GRAS status of the use of sodium metasilicate in animal feed and pet food. As indicated in the proposal, this action does not affect the current regulatory status of sodium metasilicate for these uses. FDA has ommitted pet and animal food uses from its GRAS review program because the agency does not have adequate information on the current use of GRAS and prior-sanctioned ingredients in pet and animal foods to evaluate the safety of these uses. Furthermore, this comment did not provide any information on the use of sodium metasilicate in pet and animal foods. Therefore, as stated in the proposal, FDA is not taking any action on the use of sodium metasilicate for pet and animal food uses.

No comment or new information was submitted in response to the proposed action on sodium zinc metasilicate. In accordance with the proposal, the agency is not affirming that the use of this ingredient is 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 food-grade specifications for sodium metasilicate used as a direct food ingredient and would incorporate those specifications into the regulation when they were developed. To date, however, work on the specifications is still incomplete. Until the specifications are developed, sodium metasilicate for direct food use must comply with the description in 21 CFR 184.1769a and be of food-grade purty (21 CFR 182.1(b)(3) and 170.30(h)(1)).

The agency has previously determined under 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 the 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 in 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 and under authority delegated to the Commissioner of Food and Drugs, Part 184 is amended as follows:

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

1. The authority citation for 21 CFR 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, 5.61.

2. By adding new § 184.1769a, to read as follows:

§ 184.1769a Sodium metasilicate.

(a) Sodium metasilicate (CAS Reg. No. 6834-92-0) is a strongly alkaline white powder. It does not occur naturally but rather is synthesized by melting sand with sodium carbonate at 1400 °C. The commercially available forms of sodium metasilicate are the anhydrous form (Na_2SiO_3), the pentahydrate ($Na_2SiO_3 \cdot 5H_2O$), and the nonahydrate ($Na_2SiO_3 \cdot 9H_2O$).

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

(c) In accordance with § 181.1(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 processing aid as defined in § 170.3(o)(24) of this chapter.

(2) The ingredient is used to treat the following foods at levels not to exceed current good manufacturing practice: for use in washing and lye peeling of fruits, vegetables, and nuts when used in accordance with § 173.315 of this chapter; for use as a denuding agent in tripe; for use as a hog scald agent in removing hair; and for use as a corrosion preventative in canned and bottled water when used in accordance with § 103.35 of this chapter.

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

Dated: August 20, 1985.

James W. Swanson,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 85-22837 Filed 9-24-85; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 510

Animal Drugs, Feeds, and Related Products; Change of Sponsor Address

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the current mailing address of Biomed Laboratories.

EFFECTIVE DATE: September 25, 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: Biomed Laboratories, 438 West Arrow Highway, Unit 30, San Dimas, CA 91773, has advised FDA of its current mailing address. The agency is amending the animal drug regulations to reflect this address.

List of Subjects in 21 CFR Part 510

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

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, Part 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR Part 510 continues 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.

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in paragraph (c)(1) in the entry for "Biomed Laboratories" and in paragraph (c)(2) in the entry "051259" by revising the sponsor's address to read "438 West Arrow Highway, Unit 30, San Dimas, CA 91773."

Dated: September 18, 1985.

Marvin A. Norcross,

Acting Associate Director for Scientific Evaluation.

[FR Doc. 85-22840 Filed 9-24-85; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 510

Animal Drugs, Feeds, and Related Products; Change of Sponsor Name

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 name for a new animal drug application (NADA) from Ohio Medical Anesthetics, A Division of BOC, Inc., to Anaquest, A Division of BOC, Inc.

EFFECTIVE DATE: September 25, 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: Anaquest, A Division of BOC, Inc., Madison, WI 53713, has informed FDA of a change in sponsor name for NADA 121-291 from Ohio Medical Anesthetics, A Division of BOC, Inc. The NADA covers use of enflurane as inhalation anesthetic for horses.

This is an administrative change that does not otherwise affect approval of the firm's NADA. The agency is amending the regulations in Part 510 to reflect the change.

List of Subjects in 21 CFR PART 510

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

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, Part 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR Part 510 continues 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. Section 510.600 is amended by removing the entry for "Ohio Medical Anesthetics" and by adding a new entry alphabetically to paragraph (c)(1) and by revising the entry for "010019" in 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
Anaquest, a division of BOC, Inc., Madison, WI 53713	010019

(2) * * *

Drug labeler code	Firm name and address
010019	Anaquest, a division of BOC, Inc., Madison, WI 53713

Dated: September 18, 1985.

Marvin A. Norcross,

Acting Associate Director for Scientific Evaluation.

[FR Doc. 85–22839 Filed 9–24–85; 8:45 am]

BILLING CODE 4160–01–M

21 CFR Part 510

Animal Drugs, Feeds, and Related Products; 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 the change of sponsor of several new animal drug applications from Ralston Purina Co. to Purina Mills, Inc.

EFFECTIVE DATE: September 25, 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: The Ralston Purina Co., St. Louis, MO 63164, advised FDA that its agricultural products division has become a wholly owned incorporated subsidiary, Purina Mills, Inc. The change is an administrative action which does not otherwise affect current manufacturing procedures, controls, or personnel. FDA is amending the regulations in 21 CFR 510.600 to reflect the new sponsor.

List of Subjects in 21 CFR Part 510

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

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, Part 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR Part 510 continues 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. Section 510.600 is amended in paragraph (c)(1) by deleting the entry "Ralston Purina Co." and by adding a new entry alphabetically, and in paragraph (c)(2) by revising the entry "017800" to read as follows:

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

* * * * *

(c) * * *

Firm name and address	Drug labeler code
Purina Mills, Inc., 835 South Eighth St., St. Louis, MO 63102	017800

(2) * * *

Drug labeler code	Firm name and address
017800	Purina Mills, Inc., 835 South Eighth St., St. Louis, MO 63102

Dated: September 18, 1985.

Marvin A. Norcross,

Acting Associate Director for Scientific Evaluation.

[FR Doc. 85–22838 Filed 9–24–85; 8:45 am]

BILLING CODE 4160–01–M

21 CFR Parts 510 and 558

New Animal Drugs for Use in Animal Feeds; Pyrantel Tartrate, Tylosin, Tylosin-Sulfamethazine

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 supplemental new animal drug applications (NADA's) providing for use of additional tylosin premix concentrations and for a change of sponsor from Central Soya Co., Inc., to Good-Life Division of Central Soya Co., Inc.

EFFECTIVE DATE: September 25, 1985.

FOR FURTHER INFORMATION CONTACT: Benjamin A. Puyot, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4913.

SUPPLEMENTARY INFORMATION: Central Soya Co., Inc., 1300 Fort Wayne Bank Bldg., Fort Wayne, IN 46802, has filed three supplemental NADA's, one providing for use of 5- and 20-gram-per-pound tylosin premixes in addition to its currently approved 10- and 40-gram-per-pound tylosin premixes, and all three for a change of sponsor name from the parent firm to a subsidiary. Affected are NADA 110–045, tylosin; NADA 128–411, tylosin/sulfamethazine; and NADA 134–286, pyrantel tartrate. The supplements are approved. Parts 510 and 558 are amended to include the added tylosin premixes and the sponsor change.

This action concerns a change of sponsor name and does not involve any other changes in the approval, including no changes in manufacturing facilities, equipment, procedures, or production personnel.

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 agency has determined under 21 CFR 25.24(d)(1)(i) (April 26, 1985; 50 FR 16636) 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.

List of Subjects

21 CFR Part 510

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

21 CFR Part 558

Animal drugs, Animal feeds.