reinstatement of the percentage threshold tests in effect prior to January 1, 1984, for Rule 14a–8(c)(12) [17 CFR 240.14a–8(c)(12) under the Securities Exchange Act of 1934 (the "Exchange Act") [15 U.S.C. 78a *et seq.* (1976 and Supp. IV 1980)]. These tests govern inclusion of previously included shareholder proposals.

I. Background

Rule 14a–8 governs the inclusion of shareholder proposals in the proxy statements distributed to security holders by registrants subject to the Commission's proxy rules under the Exchange Act. Prior to August 1983, paragraph (c)(12) of the rule provided that a registrant could omit from its proxy material any shareholder proposal substantially the same as a proposal previously included in the registrant's proxy material for a meeting of security holders held within the preceding 5 calendar years, where the proposal:

1. If Submitted once during such preceding period, received less than 3 percent of the total number of votes cast in regard thereto;

2. If submitted twice during the period, at its second submission received less than 6 percent of the total number of votes cast in regard thereto; or

3. If submitted three or more times during the period, at its most recent submission received less than 10 percent of the total number of votes cast in regard thereto.

On August 16, 1983, the Commission adopted a number of amendments to Rule 14a–8, including amendments to paragraph (c)(12) of the rule.[1] These amendments became effective January 1, 1984. Rule 14a–8(c)(12) was amended to apply to shareholder proposals relating to "substantially the same subject matter" as proposals previously submitted to security holders in a registrant's proxy material. The rule also was revised to increase the threshold percentages for resubmission from 3 percent to 5 percent for proposals submitted only once previously, and from 6 percent to 8 percent for proposals twice previously submitted. The percentage required for shareholder proposals previously submitted three or more times remained the same.

On Decemer 19, 1984, several shareholder proponents filed suit in the United States District Court for the District of Columbia, seeking to have the higher threshold percentage tests vacated and the lower percentage requirements previously in effect reinstated.[2] On September 13, 1985, the district court granted the plaintiff's motion for summary judgment. The court issued an order vacating the higher percentage thresholds then in effect under Rule 14a–8(c)(12) and directing the Commission to reinstate the percentage thresholds in effect prior to January 1, 1984.

II. Discussion of Reinstated Rule 14a–8

In accordance with the order of the district court, the threshold percentage tests in effect under Rule 14a–8(c)(12) prior to January 1984 are hereby reinstated. Accordingly, the rule provides that a proposal will be eligible for resubmission if it receives a 3 percent vote the first time it is included in a registrant's proxy material, or a 6 percent vote the second time it is included. The Commission will monitor the effect of the reinstated rule during this proxy season and determine thereafter whether it is appropriate to publish for public comment further changes in the threshold percentage tests for resubmission of shareholder proposals under Rule 14a–8(c)(12).

It should be noted in connection with the change in the Rule 14a–8(c)(12) percentages that pursuant to section 23(a)(1) of the Exchange Act, registrants who had previously omitted shareholder proposals in good faith in conformity with the vacated percentages while they were in effect are not subject to Exchange Act liability for such action. Further, the staff's interpretive views under Rule 14a–8(c)(12) will remain unchanged except as to the threshold percentage tests.

III. List of Subjects in 17 CFR Part 240

Reporting and recordkeeping requirements, Securities.

IV. Statutory Authority and Findings

The Commission hereby adopts the amendments to Rule 14a–8 pursuant to its statutory authority under sections 14(a) and 23(a) of the Securities Exchange Act of 1934, sections 12(e) and 20(a) of the Public Utility Holding Company Act of 1935, and sections 20(a) and 38(a) of the Investment Company Act of 1940. As required by section 23(a) of the Exchange Act, the Commission has considered the impact that this rulemaking action would have on competition and has concluded that the amendments would impose no significant burden on competition not necessary or appropriate in furtherance of the purpose of the Exchange Act.

V. Text of Amendments

In accordance with the foregoing, Title 17, Chapter II of the Code of Federal Regulations is amended as follows:

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

1. The authority citation for Part 240 continues to read as follows: (Citations before * * * indicate general rulemaking authority).

Authority: Sec. 23, 48 Stat. 901, as amended 15 U.S.C. 78w. * * * § 240.14a–8 also issued under Section 14, 15 U.S.C. 78n.

2. In § 240.14a–8, paragraphs (c)(12) (i) and (ii) are revised to read as follows:

§ 240.14a–8 Proposals of security holders.

* * * * *

(c) * * *

(12) * * *

(i) If the proposal was submitted at only one meeting during such preceding period, it received less than three percent of the total number of votes cast in regard thereto; or

(ii) If the proposal was submitted at only two meetings during such preceding period, it received at the time of its second submission less than six percent of the total number of votes cast in regard thereto; or

* * * * *

By the Commission.

John Wheeler,

Secretary.

November 14, 1985.

[FR Doc. 85–27891 Filed 11–21–85; 8:45 am]

BILLING CODE 8010–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Parts 375 and 385

[Docket No. RM86–1–000]

Revisions to Rules of Practice and Procedure and Delegation to the Chief Administrative Law Judge; Order No. 437

Issued November 13, 1985.

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Final rule.

SUMMARY: To increase administrative efficiency and reduce the burden on participants to certain proceedings, the Federal Energy Regulatory Commission (Commission) is issuing a final rule amending its Rules of Practice and Procedure to delegate to the Chief

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[1] See Release No. 34–20091 (August 23, 1983), 48 FR 38218. The revisions were proposed in Release No. 34–19135 (October 14, 1982), 47 FR 47420.

[2] *United Church Board For World Ministries* v. *SEC*, No. 84–3273 (D.D.C. September 13, 1985).

Administrative Law Judge authority to change the close-of-record date, for good cause, in proceedings under Subpart E of Part 385 of the Commission's rules.

EFFECTIVE DATE: November 13, 1985.

FOR FURTHER INFORMATION CONTACT: Penelope S. Ludwig, Office of the General Counsel, Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426, (202) 357–8483.

SUPPLEMENTARY INFORMATION:

Before Commissioners: Raymond J. O'Connor, Chairman; A.G. Sousa, Charles G. Stalon, Charles A. Trabandt and C.M. Naeve.

I. Introduction

The Federal Energy Regulatory Commission (Commission) is delegating to the Chief Administrative Law Judge (Chief Judge) the authority to change, for good cause shown, the close-of-record date in proceedings under Subpart E of Part 385[1] of the Commission's rules of practice and procedure.

II. Discussion

Recently the Commission has issued numerous orders setting the appropriateness of certain filings for hearing,[2] a date by which the record in the proceeding must close, and directing the Presiding Administrative Law Judge (Presiding Judge) to conduct a hearing on an expedited basis to meet that record-closing date. However, in several of these proceedings, participants have sought an extension or a suspension of the record closing date.[3]

Since the Commission set the closing date, only the Commission is authorized to modify the close-of-record date in these proceedings, under the Commission's current practice. Any request for a change of the date requires participants to make motions to the Presiding Judge who must in turn forward the request to the Chief Judge who certifies the motion to the Commission along with his recommendation as to the proper disposition of the request.

This procedure results in participants filing numerous documents for immediate consideration of the judges and the Commission. The Commission finds that the current procedures for a modification to the close-of-record date are burdensome and cause undue delay. Therefore, to expedite the processing of such motions, reduce the burden on the participants, and make more efficient use of the participants' resources, the Commission is delegating to the Chief Judge authority to change the close-of-record date for good cause shown. Accordingly, requests for modification to the close-of-record date are to be made directly to the Chief Judge, who will now have the authority to change the close-of-record date for good cause. This final rule codifies this delegation of authority in 18 CFR 375.304(d).

Finally, the rule modifies Rule 503[4] of the Commission's rules of practice and procedure to codify the procedures for requesting a change in a close-of-record date set by the Commission. Decisions to extend the close-of-record date under this delegation may be appealed only under Rule 1902.[5]

III. Effective Date

Pursuant to Section 4 of the Administrative Procedure Act, 5 U.S.C. 553(b) (1982), this rule is issued without prior notice and comment because it is a rule of agency organization, procedure, or practice that will not alter the substantive rights or interests of any interested persons. Specifically, this rule only delegates to the Chief Judge authority to modify the close-of-record date for good cause. In addition, any ruling by the Chief Judge on a request to modify a close-of-record date may be appealed.

Generally, a rule becomes effective not less than 30 days after it is published in the Federal Register. A rule may become effective sooner if it is an interpretive rule or policy statement, if it relieves a restriction or grants an exemption, or if the agency finds good cause to do so.[6] The Commission finds that this rule will expedite proceedings and make more effective use of the Commission's resources and will benefit participants in Commission proceedings by removing restrictions imposed by current regulations. For these reasons, the Commission finds good cause to make this rule effective on issuance.

List of Subjects

18 CFR Part 375

Authority delegations (Government agencies), seals, insignia, Sunshine Act.

18 CFR Part 385

Administrative practice and procedure.

In consideration of the foregoing, the Commission amends Parts 375 and 385 of Chapter I, Title 18, *Code of Federal Regulations*, as set forth below.

By the Commission. Commissioners Trabandt and Naeve voted present.

Lois D. Cashell,

Acting Secretary.

PART 375—[AMENDED]

1. The authority citation for Part 375 continues to read as follows:

Authority: Department of Energy Organization Act (42 U.S.C. 7101–7352) E.O. 12009, 3 CFR, 1977 Comp., p. 142; Administrative Procedure Act (5 U.S.C. 553); Federal Power Act (16 U.S.C. 791–828c), as amended; Natural Gas Act (15 U.S.C. 717–717w), as amended; Natural Gas Policy Act of 1978 (15 U.S.C. 3301 et seq.); Public Utility Regulatory Policies Act of 1978 (16 U.S.C. 2601 et seq.) unless otherwise noted.

2. Section 375.304 is amended by redesignating paragraphs (b) and (c) as paragraphs (c) and (d), respectively, and by adding a new paragraph (b) to read as follows:

§ 375.304 Delegations to the Administrative Law Judges.

* * * * *

(b) For those proceedings pending under Subpart E of Part 385, the Chief Administrative Law Judge may consolidate for hearing two or more proceedings on any or all issues, sever two or more proceedings or issues in a proceeding, and extend any close-of-record date ordered by the Commission in a proceeding.

* * * * *

PART 385—[AMENDED]

3. The authority citation for Part 385 continues to read as follows:

Authority: Department of Energy Organization Act, 42 U.S.C. 7101–7352 (1982); Executive Order 12,009, 3 CFR 142 (1978); Administrative Procedure Act, 5 U.S.C. 551–557 (1982); Independent Offices Appropriations Act, 31 U.S.C. 9701 (1982); Natural Gas Act, 15 U.S.C. 717–717z (1982); Federal Power Act, 16 U.S.C. 791a–828c (1982); Natural Gas Policy Act, 15 U.S.C. 3301–3432 (1982); Public Utility Regulatory Policies Act, 16 U.S.C. 2601–2645 (1982); Interstate Commerce Act, 49 U.S.C. 1–27 (1976), unless otherwise noted.

4. Section 385.503 is amended by revising the title, by redesignating the existing paragraph as "(a)", and by adding a new paragraph (b) to read as follows:

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[1] 18 CFR Part 385, Subpart E (1985).

[2] Texas Gas Transmission Corp., 31 FERC ¶ 61,236 (1985); Penn-York Energy Corp., 31 FERC ¶61,236 (1985); U–T Offshore Sys., 29 FERC ¶ 61,352 (1984); KN Energy Sys., Inc., 29 FERC ¶ 61,265 (1984).

[3] Texas Gas Transmission Corp., 33 FERC ¶ 63,000 (1985); Penn-York Energy Corp., 32 FERC ¶ 61,209 (1985); U–T Offshore Sys., 31 FERC ¶ 61,225 (1985); High Island Offshore Sys., 31 FERC ¶ 61,222 (1985).

[4] 18 CFR 385.503 (1985). The rule also codifies in new § 375.304 the consolidation and severance powers of the Chief Judge which were previously only referenced in § 385.503.

[5] 18 CFR 1902 (1985).

[6] U.S.C. 553(d) (1982).

§ 385.503 Consolidation, severance and extension of close-of-record date by Chief Administrative Law Judge (Rule 503)

* * * * *

(b) If the Commission orders that the presiding officer close the record in any proceeding by a specific date, the Chief Administrative Law Judge may, upon motion or otherwise, extend the close-of-record date for good cause. This staff action may be appealed to the Commission only under Rule 1902.

[FR Doc. 85-27933 Filed 11-21-85; 8:45 am]

BILLING CODE 6717-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 107

[Docket No. 82N-0270]

Exempt Infant Formula

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Infant Formula Act of 1980 exempts from some of its requirements specialty infant formulas that are intended for use by infants with special medical or dietary needs. The Food and Drug Administration (FDA) is establishing the terms and conditions under which those infant formulas will continue to be exempt. FDA is also establishing quality control, nutrient, and labeling requirements for exempt formulas.

EFFECTIVE DATE: February 20, 1986. For additional information concerning this effective date, see "Paperwork Reduction Act of 1980" appearing in the preamble of this document.

FOR FURTHER INFORMATION CONTACT: Nicholas Duy, Center for Food Safety and Applied Nutrition (HFF-204), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-245-3117.

SUPPLEMENTARY INFORMATION:

Background

In the **Federal Register** of July 12, 1983 (48 FR 31875), FDA published a proposed rule (21 CFR Part 107) for exempt infant formulas (those formulas represented and labeled for use by an infant who has an inborn error of metabolism or a low birth weight or who otherwise has an unusual medical or dietary problem). The agency proposed to create two broad categories of exempt formulas: (1) Those formulas that are generally available at the retail level and (2) those formulas that are not generally available at the retail level.

The agency proposed that manufacturers of exempt infant formula that are generally available at the retail level be required to meet the quality control requirements for regular infant formula unless specific deviations are justified. Manufacturers of infant formulas that are not generally available at the retail level would be required to establish an appropriate quality control procedure.

The agency further proposed that: (1) All exempt formulas comply with the nutrient and labeling requirements applicable to regular infant formulas, unless the manufacturer justifies specific deviations; (2) manufacturers submit to FDA detailed information about each exempt infant formula produced; and (3) after reviewing submitted information and other information available to the agency, FDA may impose additional or modified requirements for a product or withdraw a product's exempt status.

The agency received 34 letters, each containing 1 or more comments, in response to the proposal from local governments, health care professionals, trade organizations, State and county departments of health, professional organizations, and consumer advocacy organizations and consumers. Most of the comments supported the overall proposal while some comments made various suggestions. Several comments did not address the issues raised by the proposal and are not addressed below.

In response to a comment, FDA added a provision to clarify that manufacturers must notify FDA of certain formulation or processing changes. The comments and the agency's responses are as follows:

General Comments

1. One comment objected to the exemption of any infant formulas.

The agency advises that Congress specifically exempted in the Infant Formula Act of 1980 those infant formulas represented and labeled for use by an infant who has an inborn error of metabolism or low birth weight, or who otherwise has an unusual medical or dietary problem. Moreover, some infants that have these medical conditions cannot survive or would become critically ill without certain specialty infant formulas that cannot meet all nutrient requirements for "regular" infant formulas.

2. A number of comments suggested that regular infant formulas and exempt infant formulas be regulated in the same manner. These comments were concerned that the agency would permit relaxed requirements for labeling, quality control, and nutrient standards for exempt infant formulas.

The agency disagrees with these comments. FDA is not regulating exempt infant formulas in the same manner that it regulates regular infant formulas because exempt formulas frequently have specialized nutrient requirements intended to address specific medical problems. In addition, by creation of a separate category of exempt infant formulas in the Infant Formula Act of 1980, Congress recognized the need for a different regulatory approach for these infant formulas. For example, special label statements may be necessary to ensure appropriate use of these infant formulas and modified quality control procedures may need to be developed because these infant formulas may be inherently difficult to manufacture or have unusual manufacturing requirements.

Congress intended that the "conditions on exemptions * * * should ensure that [exempt] formulas are manufactured to the same high standards of quality required of formulas for normal infants." (S. Rept. No. 96-916, 96th Cong., 2d Sess. 10 (August 26, 1980) and H. Rept. No. 96-936, 96th Cong., 2d Sess. 10 (May 12, 1980)). Thus, the agency will permit deviations from the nutrient and labeling requirements that apply to regular formulas only when manufacturers have submitted sufficient medical, nutritional, scientific, or technological rationale to support the deviations. In addition, for exempt formulas that are generally available at the retail level, manufacturers will have to justify any deviations from the quality control requirements that apply to regular formulas.

3. One comment stated that the proposal would virtually repeal the exemptions granted by Congress in the Infant Formula Act of 1980 by establishing terms and conditions which subject exempt infant formulas to the full scope of the requirements of that act.

The agency disagrees. Section 412(f)(2) of the Infant Formula Act of 1980 states that "the Secretary may by regulation establish terms and conditions for the exemption of an infant formula from the requirements of subsections (a) and (b). An exemption of an infant formula under paragraph (1) may be withdrawn by the Secretary if such formula is not in compliance with applicable terms and conditions * * *."

As discussed in the preamble to the proposal, the agency believes that the provisions of the final rule adequately assure the quality of exempt infant formulas, while avoiding excessive regulation of such products. Contrary to

the comment's assertion, the full scope of the Infant Formula Act of 1980 will not be applied to all exempt infant formulas. Manufacturers of certain types of exempt infant formulas will be permitted to use alternative quality control procedures, and manufacturers of all exempt infant formulas may deviate from other requirements when the deviations are justified.

4. One comment objected to the proposal because requiring the submission of information in support of deviations would discourage the development and availability of new specialty infant formulas and possibly eliminate needed existing exempt infant formulas.

The agency disagrees. Providing this information to the agency should not be a significant burden to the manufacturer because the manufacturer must have the information in its possession in order to make sound decisions on the formulation, manufacture, and labeling of an exempt infant formula. The Center for Food Safety and Applied Nutrition will review submitted information in support of deviations and withdraw exemptions only when the agency concludes that: (1) Quality control procedures are not adequate to ensure that the formula contains all necessary nutrients; (2) deviations in nutrient levels are not supported by generally accepted scientific, nutritional, or medical rationale; (3) deviations from labeling requirements are not necessary or additional labeling is necessary to provide appropriate directions for preparation and use of the infant formula.

5. One comment suggested that a draft regulation previously submitted by the Infant Formula Council [a trade association that represents infant formula manufacturers] be substituted in its entirety for FDA's proposal.

The agency has considered the Infant Formula Council's recommendation. Based on this recommendation the agency developed the two-tier concept. As indicated in paragraph 2 of this document, Congress has stated that "conditions on exemptions * * * should ensure that such formulas are manufactured to the same high standards of quality as required of formulas for normal infants." The agency did not adopt the Infant Formula Council's recommendation in its entirety because it did not include any significant regulatory requirements through which FDA could ensure this same high standard of quality for exempt infant formulas.

6. One comment suggested that exempt infant formulas not be sold at the retail level.

The agency advises that Congress has not given it the legal authority to prohibit the sale of a food or the authority to seize a food unless it is adulterated or is misbranded. Furthermore, FDA has no data to suggest that exempt infant formulas present a safety hazard when appropriate quality control procedures and labeling are used. Therefore, the agency has no legal or scientific basis for prohibiting their sale at the retail level.

Definitions

7. One comment suggested that the definition of exempt infant formula include only those formulas that are "intended for commercial or charitable distribution" to distinguish them from those products used in clinical studies or other experimental studies.

The agency agrees and has revised § 107.3[a] accordingly.

8. One comment suggested revising the definition of manufacturer (§ 107.3[b]) so that the words "infant formula" are substituted for the word "product."

The agency agrees and has revised § 107.3(b) accordingly.

Terms and Conditions

9. One comment suggested abolishing the two-tier system [that distinguishes infant formulas that are generally available at the retail level (§ 107.50(b)) from those that are not generally available at the retail level (§ 107.50(c)) because both categories are subject to virtually the same requirements.

The agency disagrees. The agency believes that this two-tier system best addresses Congress' dual concern about: (1) The need to make special infant formulas available without the imposition of cumbersome regulations which may discourage formula manufacturers from committing resources into this vital public service, and (2) ensuring that such formulas are manufactured to the same high standards of quality required for formulas for normal infants.

The agency also believes that exempt infant formulas that are not generally available at the retail level are more likely to require alternative quality control procedures because of their unique nutrient content or their production in smaller quantities, which may lead to unique processing procedures. This two-tier system will help ensure their continued development and availability for a restricted market. For these reasons, the agency concludes that a more flexible approach to quality control for these products is warranted.

10. One comment suggested that the second sentence in § 107.50(b)(1) be deleted. The comment contended that FDA should not characterize medical or dietary conditions as not clinically serious or life-threatening unless there is scientific support for its characterization.

The agency is not deleting this sentence from the final rule. For example, some exempt infant formulas that are generally available to the public at the retail level are represented and labeled for use for the dietary management of carbohydrate intolerances or impaired fat absorption. FDA does not consider these conditions to be clinically serious.

11. One comment opposed the submission of labeling in order to retain the exempt status of an infant formula.

The agency advises that labeling that may describe in greater detail than the label the product's intended uses is necessary to determine all uses that are being promoted for an infant formula. With this information, the agency will be in a better position to determine if the nutrient content and formulation are useful in the dietary management of each of the uses claimed. Therefore, the requirement for submission of labeling has been retained.

12. One comment suggested that notification be submitted 90 days in advance of any change in composition, quality control procedures, nutrient specifications, or labeling.

The agency agrees that it should be notified before any change in ingredients or processes that may result in an adverse impact on levels of nutrients or the availability of nutrients is instituted. The agency considers this notification requirement to be implicit in proposed § 107.50(b)(4). However, in the interest of clarity the agency has redesignated proposed § 107.50(b)(4) as § 107.50(b)(5) and added a new paragraph (b)(4) in the final rule to include explicitly this requirement.

However, the agency does not believe that it is necessary to require notification 90 days in advance of reformulation or processing changes. Similarly, the agency is also not requiring agency notification for changes in quality control procedures or labeling. Section 412(b)(3) of the Infant Formula Act of 1980 contains a notification requirement for regular infant formulas. That provision does not require advance notice of reformulation or processing changes, or any notice of changes in quality control procedures or labeling.

13. One comment asserted that requiring the submission to FDA of the

medical, nutritional, scientific, or technological rationale in support of a requested deviation constitutes premarket clearance, which is manifestly beyond the authority granted by the Infant Formula Act of 1980.

The agency disagrees. Infant formulas that are represented and labeled for use by an infant that has an inborn error of metabolism, low birth weight, or otherwise has an unusual medical or dietary problem are, by the terms of the Infant Formula Act of 1980, exempt infant formulas. Written approval by the agency is not required before marketing may be initiated for these infant formulas. As provided for in section 412(f)(2) of the Infant Formula Act of 1980, the agency is merely providing procedures for manufacturers to notify the agency of their exempt infant formulas and the reasons for the need for an exemption. If those reasons conform to generally accepted scientific, nutritional, or medical rationale, exempt status will not be withdrawn.

14. One comment recommended that FDA require manufacturers to submit "medical, nutritional, scientific, *and* technological rationale" in support of deviations from requirements of the Infant Formula Act of 1980 or agency regulations, in lieu of the proposed requirement for submitting the "medical, nutritional, scientific, *or* technological rationale."

The agency is not revising § 107.50(b)(5) and (c)(5) because there will be submissions for which all of this information will not be appropriate. For example, in some instances a technological rationale for a deviation will not exist.

15. One comment suggested that the medical, nutritional, scientific, or technological rationale submitted to support deviations include summaries of animal and human clinical investigations undertaken to support the safety and appropriateness of the infant formula.

The agency considers data from animal and human clinical investigations to be part of the medical, nutritional, scientific, or technological rationale to be submitted in support of a deviation. However, to clarify any misunderstanding, the agency is revising § 107.50(b)(5) (proposed § 107.50(b)(4)) and § 107.50(c)(5) to refer to appropriate animal or human clinical studies as part of a manufacturer's submission.

16. One comment objected to proposed § 107.50(d) because it would provide for the withdrawal of an exemption for an exempt infant formula that is properly labeled, was manufactured using acceptable quality control procedures, and has a nutrient level that is safe but may not conform to generally accepted scientific, nutritional, or medical rationale for treatment of a medical condition. The comment recommended that an exemption be withdrawn only upon a determination that the product, as formulated, presents a risk to health.

The agency disagrees. The exemption provision in the Infant Formula Act of 1980 is intended to allow deviations from the standards set by the agency for regular infant formulas only for the dietary management of an inborn error of metabolism, low birth weight, or other unusual medical or dietary problem. Thus, deviations or exemptions from the Infant Formula Act of 1980 and regulations promulgated by the agency must be justified in terms of some medical or dietary need. Exemptions that are not so justified are not authorized by the Infant Formula Act of 1980 and would serve no public health purpose. In addition, if risk to health was the only criterion for withdrawing exemptions, this would shift the burden of making this determination, and therefore its justification, to the agency. FDA does not believe that Congress intended such a result. Therefore, FDA has not revised § 107.50(d)(1) based on this comment.

17. One comment suggested that the statement "For Use By Infants Who Have Inborn Errors of Metabolism or Low Birth Weight, or Who Otherwise Have Unusual Medical or Dietary Problems" appear on the label, labeling, and advertising of an exempt infant formula. Several comments suggested requiring a clear label declaration that the formula is an exempt infant formula or a label statement of the specific dietary problem for which the formula is intended.

The agency agrees with the thrust of these comments and will require clear label statements to indicate the special nature of each exempt infant formula. However, the agency is not requiring one label statement for all exempt infant formulas because it may not be applicable to all products. Therefore, the agency is not making the suggested change and will consider label declarations on a case-by-case basis.

18. One comment suggested that scientific, technical, and medical personnel, including at least one pediatrician outside the Center for Food Safety and Applied Nutrition, be included in the review process for manufacturers' submissions.

The agency advises that the Center for Food Safety and Applied Nutrition does utilize personnel (including pediatricians) throughout the agency and will, when the situation warrants, continue to do so.

19. One comment suggested that the final determination to continue or terminate an exemption be made by the Commissioner of Food and Drugs and not the Director of the Center for Food Safety and Applied Nutrition.

The agency advises that the Commissioner upon an appeal under § 107.50(d)(2)(i) makes the final decision for the agency. Therefore, no changes are necessary based on this comment.

20. One comment suggested that § 107.50(d)(2)(ii) be revised so that a product would not be required to comply with the nutrient requirements of the Infant Formula Act of 1980 when its exempt status is withdrawn.

The agency disagrees. When a product does not have exempt status or when exempt status is withdrawn, the manufacturer must comply with all requirements and regulations governing infant formulas, including the nutrient requirements of the Infant Formula Act of 1980. Therefore, FDA has not revised § 107.50(d)(2)(ii).

21. One comment suggested that § 107.50(d)(2)(ii) be revised to read "the manufacturer shall comply with the nutrient requirements of section 412(a)(2) of the act" rather than "section 412 of the act or of regulations promulgated under section 412(a)(2) of the act."

The agency advises that section 412(a)(2) of the Infant Formula Act of 1980 does not contain nutrient requirements. This section merely gives the agency the authority to promulgate regulations to revise the nutrient requirements set out in section 412(g) of that act. Therefore, the suggested change is not reflected in this final rule.

22. One comment suggested that § 107.50(d)(2)(iii) be revised by deleting the word "may" so that a product's exempt status will be withdrawn only upon a determination of a health hazard and not on the speculation that a health hazard may exist. The comment stated that this is analogous to section 412(c) of the Infant Formula Act of 1980, in which Congress decided that reporting by a manufacturer of an adulterated or misbranded product should be limited to those circumstances presenting a risk to health.

The agency disagrees. The agency does not believe that the requirements of § 107.50(d)(2)(iii) are analogous to the requirements of section 412(c) of the Infant Formula Act of 1980. Deleting the word "may" in § 107.50(d)(2)(iii) would place the burden of proof on determining a hazard to health on FDA. FDA does not believe that Congress

intended such a result. In comparison, section 412(c) of the act pertains to the legal obligations of a manufacturer. Therefore, FDA has not revised § 107.50(d)(2)(iii) to include this suggestion.

23. One comment suggested that the word "may" be deleted in § 107.50(e)(2) in the sentence "* * * or when there is an exempt infant formula that is otherwise adulterated or misbranded and that may present a risk to human health." The comment stated that deletion of the word "may" would make this section consistent with the requirements of section 412(c)(1)(B) of the Infant Formula Act of 1980, which reflects Congress' decision that such reporting should be limited to those circumstances presenting a risk to health, and that such reports should not be based upon speculation.

The agency agrees with the thrust of this comment and has revised § 107.50(e)(2) to be consistent with section 412(c)(1)(B) so that the section now reads "* * * or when there is an exempt infant formula that may be otherwise adulterated or misbranded and if so adulterated or misbranded presents a risk to human health."

24. One comment suggested that the agency make a final determination of the acceptability of information submitted by the manufacturer within 60 days of submission. The comment stated that this would minimize the possibility of the agency having to withdraw the exempt status of an infant formula after distribution has begun and that such a time frame would allow manufacturers to plan the orderly manufacture, packaging, and distribution of an exempt infant formula.

The agency disagrees. Exemptions to the Infant Formula Act of 1980 are provided by the act itself. The agency need only respond to a submission if it does not comply with the criteria established in this final rule. The agency does not believe it is appropriate to require a response prior to marketing each product because this would constitute procedures resembling premarket clearance.

25. One comment suggested the creation of an advisory committee, within the American Academy of Pediatrics, to review exempt infant formulas for appropriateness of their intended uses and nutritional adequacy.

The agency agrees that this is one way for outside experts to review information submitted in support of continued exemptions, and is considering it along with other alternatives.

Economic Considerations

In accordance with Executive Order 12291, FDA has analyzed the economic impacts of this final rule. In a previous action FDA determined that the economic impacts of rules governing quality control and labeling of infant formulas, including both exempt and nonexempt formulas, were not major as defined by the Order. The economic impact of this final rule, representing a part of that total, is estimated to be a one-time cost of $20,000. This amount represents the cost of data submission and label modification. The total cost associated with this final rule is also insufficient to warrant designation as a major rule under any of the criteria specified in Executive Order 12291.

Furthermore, in accordance with the Regulatory Flexibility Act, the agency has considered the effect that this final rule will have on small entities, including small businesses, and has concluded that small firms will not bear excessive or unreasonable burdens as a result of these regulations. The agency estimates that not more than five firms, including both large and small, will be immediately affected by this final rule, and the likelihood of numerous future entrants in this product line is minimal. Moreover, the total cost of this final rule on all active exempt formula manufacturers is estimated to be $20,000. Therefore, the agency certifies in accordance with section 605(b) of the Regulatory Flexibility Act that there will be no significant economic impact on a substantial number of small entities resulting from this action. A copy of the threshold assessment may be seen in the Dockets Management Branch.

Environmental Considerations

The agency has determined pursuant to 21 CFR 25.24(b)(12) (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.

Paperwork Reduction Act of 1980

Section 107.50 of this final rule contains collection of information requirements that were submitted for review and approval to the Director of the Office of Management and Budget (OMB), as required by section 3507 of the Paperwork Reduction Act of 1980. The requirements were approved and assigned OMB control number 0910-0158.

In response to comments, FDA amended § 107.50 of this final rule by adding new paragraph (b)(4) to make explicit a notification requirement that was implicit in the proposal. In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35), the collection of information requirement contained in new § 107.50(b)(4) in this final rule will be submitted for approval to OMB. This requirement will not be effective until FDA obtains OMB approval. FDA will publish a notice concerning OMB approval of this requirement in the **Federal Register** prior to February 20, 1986.

List of Subjects in 21 CFR Part 107

Food labeling, Infants and children, Infant formula, Nutrient information, Quality control.

Therefore, under the Federal Food, Drug, and Cosmetic Act, Part 107 is amended as follows:

PART 107—INFANT FORMULA

1. The authority citation for 21 CFR Part 107 is revised to read as follows:

Authority: Secs. 201(n) and (aa), 403(a) and (j), 412, 701, 52 Stat. 1041 as amended, 1047–1048 as amended, 1055–1056 as amended, 94 Stat. 1190–1193 (21 U.S.C. 321(n) and (aa), 343(a) and (j), 350a, 371); 21 CFR 5.11; § 107.100 issued only under secs. 201(aa), 412, 701(a), 52 Stat. 1055, 94 Stat. 1190–1193 (21 U.S.C. 321(aa), 350a, 371(a)); 21 CFR 5.11; Subparts A and C are issued under secs. 201(n) and (aa), 403(a), 412, 701(a), 52 Stat. 1041 as amended, 1047 as amended, 1055, 94 Stat. 1190 (21 U.S.C. 321(n) and (aa), 343(a), 350a, 371(a)); 21 CFR 5.11.

2. By adding Subparts A and C to read as follows:

Subpart A—General Provisions

Sec.
107.3 Definitions.
* * * * *

Subpart C—Exempt Infant Formulas

107.50 Terms and conditions.
* * * * *

Subpart A—General Provisions

§ 107.3 Definitions.

The following definitions shall apply, in addition to the definitions contained in section 201 of the Federal Food, Drug, and Cosmetic Act (the act):

Exempt formula. An exempt infant formula is an infant formula intended for commercial or charitable distribution that is represented and labeled for use by infants who have inborn errors of metabolism or low birth weight, or who otherwise have unusual medical or dietary problems.

Manufacturer. A manufacturer is a person who prepares, reconstitutes, or otherwise changes the physical or chemical characteristics of an infant formula or packages the infant formula in containers for distribution.

References. References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21, unless otherwise noted.

* * * * *

Subpart C—Exempt Infant Formulas

§ 107.50 Terms and conditions.

(a) *Terms and conditions.* Section 412(f)(1) of the act exempts from the requirements of section 412(a), (b), and (c)(1)(A) of the act infant formulas that are represented and labeled for use by an infant who has an inborn error of metabolism or low brith weight or who otherwise has an unusual medical or dietary problem, if such formulas comply with regulations prescribed by the Secretary. The regulations in this subpart establish the terms and conditions that a manufacturer must meet with respect to such infant formulas.

(b) *Infant formulas generally available at the retail level.* (1) These exempt infant formulas can generally be purchased from retail store shelves that are readily available to the public. Such formulas are also typically represented and labeled for use to provide dietary management for diseases or conditions that are not clinically serious or life-threatening, even though such formulas may also be represented and labeled for use in clinically serious or life-threatening disorders.

(2) Except as provided in paragraph (b)(4) and (5) of this section, an infant formula manufacturer shall, with respect to each formula covered by this paragraph, comply with the nutrient requirements of section 412(g) of the act or of regulations promulgated under section 412(a)(2) of the act, the quality control procedure requirements of Part 106, and the labeling requirements of Subpart B of this part.

(3) To retain the exempt status of an infant formula covered by this paragraph, the manufacturer shall submit to the Food and Drug Administration (FDA), at the address specified in paragraph (e)(1) of this section, on or before May 21, 1986, or on or before the 90th day before the first processing of the infant formula for commercial or charitable distribution, whichever occurs later, the label and other labeling of the infant formula, a complete quantitative formulation for the infant formula, and a detailed description of the medical conditions for which the infant formula is represented. FDA will review the information under paragraph (d) of this section.

(4) To retain the exempt status of an infant formula covered by this paragraph, when any change in ingredients or processes that may result in an adverse impact on levels of nutrients or availability of nutrients is instituted, the manufacturer shall submit to FDA at the address specified in paragraph (e)(1) of this section, before the first processing of the infant formula, the label and other labeling of the infant formula, a complete quantitative formulation for the infant formula, a detailed description of the reformulation and the rationale for the reformulation, a complete description of the change in processing, and a detailed description of the medical conditions for which the infant formula is represented. FDA will review that information under paragraph (d) of this section.

(5) A manufacturer may deviate from the requirements of paragraph (b)(2) of this section only with respect to those specific requirements for which it submits to FDA, at the address specified in paragraph (e)(1) of this section, the medical, nutritional, scientific, or technological rationale (including any appropriate animal or human clinical studies). FDA will review that information under paragraph (d) of this section.

(c) *Infant formulas not generally available at the retail level.* (1) These exempt infant formulas are not generally found on retail shelves for general consumer purchase. Such formulas typically are prescribed by a physician, and must be requested from a pharmacist or are distributed directly to institutions such as hospitals, clinics, and State or Federal agencies. Such formulas are also generally represented and labeled solely to provide dietary management for specific diseases or conditions that are clinically serious or life-threatening and generally are required for prolonged periods of time. Exempt infant formulas distributed directly to institutions such as hospitals, clinics, and State or Federal agencies that are of the same formulation as those generally available at the retail level are subject to the requirements of paragraph (b) of this section rather than to the requirements of this paragraph.

(2) Except as provided for in paragraph (c)(5) of this section, an infant formula manufacturer shall, with respect to each formula covered by this paragraph, comply with the nutrient requirements of section 412(g) of the act or of regulations promulgated under section 412(a)(2) of the act, and the labeling requirements of Subpart B of this part.

(3) Each manufacturer of an infant formula covered by this paragraph shall establish quality control procedures designed to ensure that the infant formula meets applicable nutrient requirements of this section, including any special nutritional characteristics for the specific disorders or conditions for which the formula is represented for use. Each manufacturer shall maintain records of such quality control procedures sufficient to permit a public health evaluation of each manufactured batch of infant formula and shall permit any authorized FDA employee at all reasonable times to have access to and to copy and verify the records referred to in this paragraph.

(4) To retain the exempt status of an infant formula covered by this paragraph, the manufacturer shall submit the information required by paragraph (b)(3) and (4) of this section.

(5) A manufacturer may deviate from the requirements of paragraph (c)(2) of this section only with respect to those specific requirements for which it submits to FDA, at the address specified in paragraph (e)(1) of this section, the medical, nutritional, scientific, or technological rationale (including any appropriate animal or human clinical studies). FDA will review that information under paragaraph (d) of this section.

(6) The requirements of this section do not apply to an infant formula specially and individually prepared for one or more specific infants on a physician's request.

(d) *FDA review of exempt status.* (1) FDA's Center for Food Safety and Applied Nutrition will review information submitted by infant formula manufacturers under paragraph (b) (3), (b) (4), or (c) (4) of this section. On the basis of such review and other information available to the agency, the Center for Food Safety and Applied Nutrition may impose additional conditions on, or modify requirements for, the quality control procedures, nutrient specifications, or labeling of an infant formula, or withdraw a product's exempt status. Such determinations will be made by the Director of the Center for Food Safety and Applied Nutrition.

(2)(i) If after completing its review of all information submitted, the Center for Food Safety and Applied Nutrition concludes that additional or modified quality control, nutrient, or labeling requirements are needed, or that a product's exempt status is withdrawn, the Center for Food Safety and Applied Nutrition will so notify the manufacturer

and this notification will specify the reasons therefor. Upon receipt of this notification, the manufacturer has 10 working days to have the decision reviewed under § 10.75 by the office of the Commissioner of Food and Drugs. A determination by the Director of the Center for Food Safety and Applied Nutrition that is not appealed becomes a final agency decision.

(ii) After a final decision by the Director or by the office of the Commissioner that a product's exempt status is withdrawn, the manufacturer shall comply with the nutrient requirements of section 412(g) of the act or of regulations promulgated under section 412(a)(2) of the act, the quality control requirements of Part 106, and the labeling requirements of Subpart B of this part.

(iii) The compliance date for the withdrawal of a product's exempt status or the imposition of additional or modified quality control, nutrient, or labeling requirements is 60 calendar days after issuance of the final decision except as otherwise provided for reasons stated in the decision. If the agency determines that a health hazard may exist and so notifies the manufacturer, withdrawal of a product's exempt status shall be effective on the date of receipt of notification from the Director of the Center for Food Safety and Applied Nutrition. Additional or modified requirements, or the withdrawal of an exemption, apply only to those formulas that are manufactured after the compliance date. A postponement of the compliance date may be granted for good cause.

(3) FDA may decide that withdrawal of an exemption is necessary when, on the basis of its review under paragraph (d)(1) of this section, it concludes that quality control procedures are not adequate to ensure that the formula contains all required nutrients, that deviations in nutrient levels are not supported by generally accepted scientific, nutritional, or medical rationale, or that deviations from Subpart B of this part are not necessary to provide appropriate directions for preparation and use of the infant formula, or that additional labeling information is necessary.

(4) FDA will use the following criteria in determining whether deviations from the requirements of this subpart are necessary and will adequately protect the public health:

(i) A deviation from the nutrient requirements of section 412(g) of the act or of regulations promulgated under section 412(a)(2) of the act is necessary to provide an infant formula that is appropriate for the dietary management of a specific disease, disorder, or medical condition;

(ii) For exempt infant formulas subject to paragraph (b) of this section, a deviation from the quality control procedures requirements of Part 106 is necessary because of unusal or difficult technological problems in manufacturing the infant formula; and

(iii) A deviation from the labeling requirements of Subpart B of this part is necessary because label information, including pictograms and symbols required by those regulations, could lead to inappropriate use of the product.

(e) *Notification requirements.* (1) Information required by paragraphs (b) and (c) of this section shall be submitted to Chief, Regulatory Affairs Staff (HFF–204), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

(2) The manufacturer shall promptly notify FDA when the manufacturer has knowledge (as defined in section 412(c)(2) of the act) that reasonably supports the conclusion that an exempt infant formula that has been processed by the manufacturer and that has left an establishment subject to the control of the manufacturer may not provide the nutrients required by paragraph (b) or (c) of this section, or when there is an exempt infant formula that may be otherwise adulterated or misbranded and if so adulterated or misbranded presents a risk of human health. This notification shall be made, by telephone, to the Director of the appropriate FDA district office specified in § 5.115. After normal business hours (8 a.m. to 4:30 p.m.), the FDA emergency number, 202–737–0448, shall be used. The manufacturer shall send a followup written confirmation to the Division of Regulatory Guidance (HFF–310), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, and to the appropriate FDA district office specified in § 5.115.

(Collection of information requirements were approved by the Office of Management and Budget and assigned OMB control number 0910–0158.)

Dated: October 23, 1985.

Frank E. Young,

Commissioner of Food and Drugs.

Margaret M. Heckler,

Secretary of Health and Human Services.

[FR Doc. 85-27736 Filed 11-21-85; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Parts 510 and 520

Animal Drugs, Feeds, and Related Products; Polyoxyethylene (23) Lauryl Ether Blocks

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by V.M.S., Inc., providing for safe and effective use of medicated blocks containing 2.2 percent polyoxyethylene (23) lauryl ether (surface-active compound) for reduction of the incidence of bloat in cattle grazing legume-rich (alfalfa, clover) pastures. The regulations are further amended to add the firm to the list of sponsors of approved NADA's.

EFFECTIVE DATE: November 22, 1985.

FOR FURTHER INFORMATION CONTACT: Adriano R. Gabuten, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4913.

SUPPLEMENTARY INFORMATION: V.M.S., Inc., P.O. box 406, Montgomery, AL 36195–6001, filed NADA 136–214 providing for free-choice administration of molasses-based, feed supplement blocks (25 pounds each) containing 2.2 percent polyoxyethylene (23) lauryl ether (surface-active compound) for reduction of the incidence of bloat in beef cattle and nonlactating dairy cattle grazing legume-rich pastures. The NADA is approved and the regulations are amended to reflect the approval. The basis of approval is discussed in the freedom of information summary. The regulations are also amended to add the firm to the list of sponsors of approved NADA's in 21 CFR 510.600(c).

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 carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence