2. A new § 154.111 is added to read as follows:

§ 154.111 Limitations on provisions in rate schedules and tariffs relating to minimum bills.

On or after October 30, 1983, any portion of any minimum commodity bill provision of any rate schedule for the sale of natural gas which provides for the recovery of purchase gas costs, fuel costs, or other variable costs which are not incurred in providing natural gas service, are inoperative and of no effect at law. Any rate schedule, filed on or after October 30, 1983, which contains a minimum commodity bill provision which provides for the recovery of purchase gas costs, fuel costs, or other variable costs, shall be rejected to the extent that it provides for the recovery of costs which are not actually incurred in rendering service.

[FR Doc. 83-23846 Filed 8-29-83; 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-0269]

Wheat Gluten, Corn Gluten, and Zein; Proposed Affirmation of GRAS Status; Extension of Comment Period

AGENCY: Food and Drug Administration.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the period for submitting comments on its proposal to affirm that wheat gluten, corn gluten, and zein are generally recognized as safe (GRAS) as direct human food ingredients. The International Wheat Gluten Association asked for the extension, and FDA is granting it.

DATE: Comments by October 12, 1983.

ADDRESS: Written comments to the Dockets Managemnet Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Leo F. Mansor, Bureau of Foods (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-426-8950.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 12, 1983 (48 FR 31887), FDA published a proposal to affirm that wheat gluten, corn gluten, and zein are GRAS as direct human food ingredients. FDA asked for comments by September 12, 1983.

By letter dated August 2, 1983, the International Wheat Gluten Association (IWGA), on behalf of 17 major wheat gluten-producing members throughout the world, asked FDA to extend the comment period by 30 days. The extension will allow time for the IWGA's members to discuss the subject at their next regular quarterly Technical Committee meeting to be held on September 12-13, 1983, and to prepare a formal response.

After carefully evaluating the request, FDA has decided to grant this very brief extension. FDA recognizes the significance of the issues involved in this matter and wishes to ensure that all interested persons have a fair amount of time for comment. Therefore, FDA has concluded that the comment period should be extended an additional 30 days.

Interested persons may, on or before October 12, 1983, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 24, 1983.

William R. Clark,

Acting Associate Director for Regulatory Affairs.

[FR Doc. 83-23705 Filed 8-29-83; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 341

[Docket No. 76N-052B]

Cold, Cough, Allergy, Bronchodilator and Antiasthmatic Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for OTC Bronchodilator Drug Products; and Reopening of Administrative Record

AGENCY: Food and Drug Administration.

ACTION: Proposed rule; reopening of administrative record.

SUMMARY: The Food and Drug Administration (FDA) is reopening the administrative record for over-the-counter (OTC) bronchodilator drug products to accept comments that have been filed with the Dockets Management Branch, FDA, since the date that the administrative record officially closed and to include the results of a recent advisory committee meeting. FDA is also reopening the administrative record for the filing of additional comments on the OTC marketing of metaproterenol sulfate metered-dose inhaler products.

DATE: Writtern comments by October 31, 1983.

ADDRESS: Comments are on file in the Dockets Management Branch (HFA-205), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, where additional written comments may be submitted.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, National Center for Drugs and Biologics (HFN-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 26, 1982 (47 FR 47520), FDA published a notice of proposed rulemaking in the form of a tentative final monograph that would establish conditions under which OTC bronchodilator drugs are generally recognized as safe and effective and not misbranded. In that document, FDA proposed OTC marketing of metaproterenol sulfate metered-dose inhaler products. Before the proposal, metaproterenol sulfate had been marketed in that dosage form as a prescription drug only.

At the time FDA proposed OTC marketing of metaproterenol sulfate metered-dose inhaler products, the agency believed that the drug was as safe but more effective than currently available OTC epinephrine products. For this reason, the agency concluded that the conversion of metaproterenol sulfate metered-dose inhaler products to OTC status would improve the overall quality of the OTC drug therapy available to persons suffering from asthma. The agency also concluded that it would be in the interest of the public health for this improvement to be effected immediately, rather than awaiting publication of a final monograph for OTC bronchodilator drugs, an event that might not occur for several years.

After the comment period on this proposal closed on December 27, 1982, two firms commenced the OTC marketing of metaproterenol sulfate in a metered-dose inhaler. Subsequently, FDA received many letters questioning the agency's decision to allow this drug to be marketed OTC. These letters criticized both the decision and the agency's failure to await comment, or seek the advice of its appropriate advisory committee, before allowing the decision to take effect.

In response to these criticisms, FDA scheduled a meeting of its Pulmonary-Allergy Drugs Advisory Committee to present the issue of the OTC marketing of metaproterenol sulfate. The advisory committee met on May 13. Presentations were made by FDA staff responsible for the decision, by several of the principal critics of the decision, by several proponents of the decision, and by representatives of one of the marketing firms, also in favor of the decision. Following these presentations, the advisory committee deliberated and, by a vote of 4 to 3, recommended to FDA that it rescind its decision to permit the OTC marketing of metaproterenol sulfate metered-dose inhaler. In the **Federal Register** of June 3, 1983 (48 FR 24925) the agency announced that metaproterenol sulfate in a metered-dose inhaler for use as a bronchodilator may not be marketed OTC at this time.

FDA has on occasion received comments bearing on a proposed rule after the closing of the administrative record. Under § 330.10(a)(10)(iii) of the procedural regulations for OTC drugs (21 CFR 330.10(a)(10)(iii)), the administrative record closes at the end of the comment period specified in the publication of the proposed rule in the **Federal Register**. Following publication of the proposed rule on OTC bronchodilator drug products, the administrative record for the submission of comments and objections closed on December 27, 1982. As provided in § 330.10(a)(10)(iii), the letters received after December 27, 1982, as well as the results of the May 13 advisory committee meeting, could not be included in the administrative record unless the Commissioner of Food and Drugs reopened the administrative record. Because these letters and the advisory committee's recommendation were part of the basis for the agency's decision to rescind the OTC marketing status of metaproterenol sulfate in a metered-dose inhaler, and because the letters and the advisory committee proceedings also contain a number of comments on epinephrine metered-dose inhaler and on metaproterenol sulfate tablets and syrup, the Commissioner is reopening the administrative record to include the letters and the minutes and transcripts of the advisory committee meeting in the record for agency consideration prior to the publication of the final rule on OTC bronchodilator drug products.

At this time, the agency is also reopening the administrative record for OTC bronchodilator drug products to accept comments relating only to the issue of the OTC marketing of metered-dose inhaler products containing metaproterenol sulfate. Additional comments on this subject only may be submitted for 60 days following this reopening of the administrative record.

The administrative record has been open for the limited purpose of allowing the submission of new data demonstrating the safety and effectiveness of conditions not classified in Category I since publication of the proposed rule for OTC bronchodilator drug products (October 26, 1982). The agency advises that the dates identified in the proposed rule (47 FR 47520) for the submission of new data by October 26, 1983, and comments on the new data by December 26, 1983, are not affected by the 60-day comment period provided for in this document.

This notice serves to inform interested persons of the existence of letters containing comments, objections, data, and information on metaproterenol sulfate metered-dose inhaler products; their availability for review at the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday; and to provide for the filing of additional written comments by October 31, 1983 on the OTC marketing of metaproterenol sulfate metered-dose inhaler products. Three copies of all comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document.

Dated: August 24, 1983.

William R. Clark,

Acting Associate Director for Regulatory Affairs.

[FR Doc. 83-23706 Filed 8-29-83; 8:45 am]
BILLING CODE 4160-01-M

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21 CFR Part 680

[Docket No. 78N-0172]

Allergenic Products; Proposed Limit of Maximum Volume in Multiple-Dose Containers; Withdrawal of Proposed Rule

AGENCY: Food and Drug Administration.

ACTION: Withdrawal of proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing a proposal that would have limited the maximum volume of Allergenic Products contained in multiple-dose containers to 30 milliliters (mL). This regulation was proposed with the intent of reducing the possibility of product contamination and to be consistent with recommendations in the United States Pharmacopeia, Nineteenth Revision ("U.S.P." XIX) regarding maximum volume of drugs in multiple-dose containers. The proposal is being withdrawn because data made available to the agency after publication of the proposal demonstrate no relationship between contamination and the volume of allergenic material in a container.

DATE: Comments by October 31, 1983.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Rada Proehl, National Center for Drugs and Biologics (HFN-813), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20205, 301-443-1306.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 14, 1978 (43 FR 30302), FDA proposed to amend § 680.2 (21 CFR 680.2) of the biologics regulations to limit the permitted maximum volume of Allergenic Products in multiple-dose containers to 30 mL. Multiple-dose containers are designed to permit the withdrawal of successive portions of the contents without affecting the strength, quality, or purity of the remaining portion. However, because multiple-dose containers may be entered several times, there is the potential danger of contamination. It would be expected that the smaller the volume of product in a container, the fewer times it would be entered, thereby minimizing the chance of introducing and exposing the product to environmental contaminants. Because there are no existing maximum volume requirements for Allergenic Products, FDA proposed that the volume of Allergenic Products in multiple-dose containers be limited to 30 mL. In addition to reducing the possibility of product contamination, the proposed amendment would have provided consistency between the biologics regulations and the recommendations in "U.S.P." XIX regarding maximum volume of drugs in multiple-dose containers which had not been applied to allergenic biological drugs.

In response to the proposal, 78 comments were received. The consensus among the comments is that there is a lack of evidence to show that larger than 30-mL containers of Allergenic Products present more risks than 30-mL containers if proper precautions are taken each time the container is entered. As expressed by one comment, "Contamination of the multidose container is a function of the care and preparation with which the user

operates." The comments also said that the cost of providing allergy medical care could only be increased as a result of the proposed limitation of container size to 30 mL. Contributing to this cost increase are the more expensive packing and shipping for smaller containers, combined with the need for increased refrigerated storage, space, e.g., two 30-mL vials occupy more space than one 50 or 60-mL vial. As additional supportive argument against requiring a maximum volume limitation of 30 mL for containers of allergenic extracts, many of the comments said most allergists buy large extract containers to be used mainly as stock containers for extraction and dilution purposes and rarely to be used as multiple-dose containers. Accordingly, the contamination risk is diminshed because of infrequent entry into the stock container.

Since the July 14, 1978 publication, FDA has reviewed data that were not previously available concerning the sterility of Allergenic Products in multiple-dose containers that demonstrate no relationship between contamination and volume of material in a container. These data were not available for public display at the time of the July 14, 1978 Federal Register publication. The agency believes it desirable, although not legally required, to receive public comments on these data. Accordingly, FDA has placed the documents containing the data on file for public review in the Dockets Management Branch, FDA, under Docket No. 78N-0172 and will accept comments on them until October 31, 1983.

All comments received on these data will become part of the administrative record for this matter and will be placed on file for public review in the Dockets Mangement Branch (address above) under Docket No. 78N-0172.

FDA will review all the comments received on these data and any other data on this issue that become available. But FDA will publish a reproposal only if comments received on these data or new data warrant it.

List of Subjects in 21 CFR Part 680

Biologics, Blood.

PART 680—ADDITIONAL STANDARDS FOR MISCELLANEOUS PRODUCTS

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 501, 510, 701, 704, 52 Stat. 1049–1050 as amended, 1055–1056 as amended, 67 Stat. 477 as amended, 76 Stat. 794 as amended (21 U.S.C. 351, 360, 371, 374)), the Public Health Service Act (sec. 351, 58 Stat. 702 as amended (42 U.S.C. 262)), and under 21 CFR 5.11 (see 47 FR 16010; April 14, 1982), the proposed amendment appearing at page 30302 in the Federal Register of July 14, 1978, to add new paragraph (e) to § 680.2 *Manufacture, of allergenic products* is withdrawn.

Dated: August 19, 1983.

Mark Novitch,

Deputy Commissioner of Food and Drugs.

Margaret M. Heckler,

Secretary of Health and Human Services.

[FR Doc. 83-23711 Filed 8-29-83; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 161

[CGO 79-131]

U.S./Canadian Cooperative Vessel Traffic Management System

Correction

In FR Doc. 83-22666, beginning on page 37433, in the issue of Thursday, August 18, 1983, make the following corrections:

1. On page 37435, in the third column, in § 161.202(a), in the first line "or less" should read "of less".

2. On page 37436, in the first column, in § 161.206(b), in the third line, "Transportation" should read "Transport"; in the second column, in the same section, in the fifth line from the top "Van couver" should read "Vancouver".

3. On page 37436, in the second column, in § 161.208(a), in the fifth line, "procedure provides" should read "procedure for use in U.S. waters if he is satisfied that such other procedure provides".

4. Also on page 37436, in the second column, in § 161.214, in the last line of the table "Van Couver" should read "Vancouver".

5. On page 37438, in the third column, in § 161.266(a), in the third line "51.3" should read "53.3".

BILLING CODE 1505-10-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-300076; PH-FRL 2424-4]

Sulfuric Acid; Proposed Exemptions From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed Rule.

SUMMARY: This document proposes that sulfuric acid that meets the Food Chemicals Codex specifications be exempted from the requirement of a tolerance when used as an inert ingredient pH control agent in pesticide formulations. This proposed regulation was requested by Dow Corning Corporation.

DATE: Written comments must be received on or before September 30, 1983.

ADDRESS: Written comments may be submitted by mail to: Registration Support and Emergency Response Branch, Registration Division (TS-767C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

In person, deliver comments to: Emergeny Response and Minor Use Section, Registration Division (TS-767C), Environmental Protection Agency, Rm. 716D, CM#2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: N. Bhushan Mandava (703-557-7700).

SUPPLEMENTARY INFORMATION: At the request of Dow Corning Corp., the Administrator proposes to amend 40 CFR 180.1001(c) by establishing an exemption from the requirement of a tolerance for sulfuric acid that meets the Food Chemical Codex specifications and is used as an inert ingredient pH control agent.

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 162.3(c), and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): solvents such as water; baits such as sugar, starches, and meat scraps; dust carriers such as talc and clay; fillers; wetting and spreading agents; propellants in aerosol dispensers; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active.

Preambles to proposed rulemaking documents of this nature include the common or chemical name of the substance under consideration, the name and address of the firm making the request for the exemption, and toxicological and other scientific bases used in arriving at a conclusion of safety in support of the exemption.

Name of inert ingredient: Sulfuric acid.

Name and address of requestor: Dow Corning Corporation, Midland, Michigan 48640.

Bases for approval—1. Sulfuric acid has been recently affirmed as generally