DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201 and 331

[Docket No. 90N-0309]

Drug Labeling; Sodium Labeling for Over-the-Counter Drugs; Proposed Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the general labeling provisions for over-the-counter (OTC) drug products to: (1) Require that the sodium content of all orally administered OTC drug products be included in labeling when the product contains 5 milligrams (mg) or more sodium per a single recommended dose, (2) require that orally administered OTC drug products containing more than 140 mg sodium in the maximum recommended daily dose be labeled with a general warning that persons who are on a sodium-restricted diet should not take the product unless directed by a doctor, and (3) provide for the voluntary use of certain descriptive terms relating to the product's sodium content. FDA is issuing this notice of proposed rulemaking in order to provide uniform sodium content labeling for all orally administered OTC drug products, and to provide for the voluntary use in OTC drug labeling of the same terms used to describe sodium content in food labeling.

DATES: Written comments by June 24, 1991. Written comments on the agency's economic impact determination by June 24, 1991.

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

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 18, 1984 (49 FR 15510), FDA published a final rule on the declaration of sodium content of foods and label claims for foods and the basis of sodium content. The final rule established 21 CFR 101.13, which provides, in part, for the use of the following descriptive terms relating to the quantitative sodium content of foods: (1) The term "sodium free" may be used on the label and in the labeling of foods that contain less than 5 mg of sodium per serving, (2) the term "very low sodium" may be used on the label and in the labeling of foods that contain 35 mg or less of sodium per serving, and (3) the term "low sodium" may be used on the label and in the labeling of foods that contain 140 mg or less of sodium per serving.

In the **Federal Register** of July 19, 1990, the agency published food labeling proposed rules on (1) reference daily intakes and daily reference values (55 FR 29476); mandatory status of nutrition labeling and nutrient content revision (55 FR 29487); and serving sizes (55 FR 29517). In these rulemakings, the agency's proposals included (1) the establishment of daily reference values (DRV's) for certain food components, including sodium (55 FR 29476 at 29483), that are important to the maintenance of good health, (2) a statement that the declaration of sodium content expressed in milligrams should remain mandatory (55 FR 29487 at 29500), and (3) an amendment to the nutritional labeling regulations to define portion size on the basis of the amount of food commonly consumed per eating occasion (55 FR 29517 at 29522).

Consumers are increasingly aware of the possible adverse health effects of sodium, but they cannot adhere to sodium-restricted diets if they do not know the sodium content of the food and other substances, such as drugs, that they ingest. The agency believes that the sodium content labeling used for foods should be extended to all orally administered OTC drug products because (1) many people are on sodium-restricted diets, (2) sodium-containing OTC drugs could, for some individuals, contribute a significant percentage of the daily intake for sodium, and (3) there is a widespread interest by consumers in reducing their sodium intake (Ref. 1).

The agency has reviewd the existing OTC drug regulations and the ongoing OTC drug rulemaking to (1) consolidate and develop uniform requirements relating to the labeling of sodium content of orally administered OTC drug products and (2) require an appropriate warning to ensure the safe use of OTC drug products that contain certain amounts of sodium in the recommended daily dose.

The existing requirement for OTC antacid drug products in § 331.30(f) (21 CFR 331.30(f)) provides that the "labeling of the product contains the sodium content per dosage unit (e.g., tablet, teaspoonful) if it is 0.2 milliequivalents (mEq) (5 mg) or higher." Section 331.30(c)(5) requires the following warning for any OTC antacid drug product that contains more than 5 mEq (115 mg) sodium in the maximum recommended daily dose: "Do not use this product except under the advice and supervision of a physician if you are on a sodium restricted diet." These requirements have been in effect since 1974, and affected OTC antacid drug products are labeled accordingly.

In the **Federal Register** of March 21, 1975 (40 FR 12902), the agency published the recommendations of the Advisory Review Panel on OTC Laxative, Antidiarrheal, Emetic, and Antiemetic Drug Products. That notice contained the Panel's recommended monographs on four drug categories—laxatives (part 334), antidiarrheals (part 335), antiemetics (part 336), and emetics (part 337). Two of those recommended monographs contained labeling requirements relating to sodium content. The Panel's recommended monographs for laxatives and antidiarrheals both required that products containing more than 15 mEq (345 mg) of sodium in the maximum recommended daily dose bear the following warnings: "Do not use this product except under the advice and supervision of a physician if you are on a low salt diet" and "Do not use this product except under the advice and supervision of a physician if you have kidney disease." In addition, both recommended monographs required a quantitative statement of sodium content per dosage unit for products containing more than 1 mEq (23 mg) of sodium per maximum daily dose.

In the **Federal Register** of January 15, 1985 (50 FR 2124), FDA published the tentative final monograph for OTC laxative drug products and revised the Panel's recommendations. The agency stated that the Panel's recommended warnings for sodium-containing laxatives were not consistent with the sodium warning required for OTC antacid drug products (21 CFR 331.30(c)(5)). (See 50 FR 2148.) To resolve this inconsistency, the agency proposed that the Panel's recommended kidney disease warning be deleted and that the sodium-restricted diet warning apply to all laxative products containing more than 5 mEq (115 mg) of sodium in the maximum recommended daily dose. The tentative final monograph for OTC laxative drug products thus provides in proposed § 334.50(b)(5) (21 CFR 334.50(b)(5)) for products containing more than 5 mEq (115 mg) of sodium in the maximum recommended daily dose: "Do not use this product if you are on a low salt diet unless directed by a doctor."

Proposed § 334.50(b)(8) of the tentative final monograph provides that any laxative drug product "containing more than 1 milliequivalent (23 milligrams) sodium per maximum daily dose shall be labeled as to the sodium content per dosage unit." This requirement was inconsistent with the final monograph for OTC antacid drug products, which required quantitative sodium-content labeling for products containing 5 mg or more per dosage unit. However, the agency proposed to retain the Panel's recommendation to require a statement of sodium content per dosage unit for all OTC laxative drug products containing more than 1 mEq (23 mg) of sodium per maximum daily dose because it would be more informative (50 FR 2148). The agency received two comments relating to sodium labeling in response to the tentative final monograph. The comments contended that the sodium labeling of OTC laxative and other drug products should be consistent with FDA's food labeling terminology. They stated that food products already bear FDA terminology and the food terminology will become the dominant system. Thus, other mandatory FDA labeling systems should be made consistent with that system. The agency is taking this approach in this current proposal for OTC drug products containing sodium.

The tentative final monograph for OTC antidiarrheal drug products (April 30, 1986; 51 FR 16138) did not include any Category I sodium-containing ingredients, and therefore did not include any recommendation for sodium labeling. Because final monographs for OTC laxative and antidiarrheal drug products have not yet been published, no OTC laxative or antidiarrheal drug product is currently required to meet these labeling requirements. Consequently, any revisions in the requirements previously proposed for these products would not adversely affect currently marketed OTC laxative and antidiarrheal drug products.

In the **Federal Register** of July 8, 1977 (42 FR 35345), the agency published the recommendations of the Advisory Review Panel on OTC Internal Analgesic, Antipyretic, and Antirheumatic Drug Products. Section 343.50(c)(8)(i) of the Panel's recommended monograph for OTC internal analgesic, antipyretic, and antirheumatic drug products contains the same quantitative labeling requirement for sodium content that appears in § 331.30(f) of the final monograph for OTC antacid drug products. Antacid products containing 0.2 mEq (5 mg) or higher of sodium per dosage unit are required to contain in their labeling the sodium content per dosage unit. In addition, in § 343.50(c)(8)(ii) the Panel's recommended monograph contains a warning alerting persons on a sodium-restricted diet not to consume internal analgesic-antipyretic products containing more than 5 mEq (125 mg) of sodium in the maximum recommended daily dose except under the advice and supervision of a physician. The sodium warning requirement recommended by the Panel incorrectly equated 5 mEq to 125 mg of sodium rather than 115 mg. (One mEq of sodium is 23 mg; 5 mEq is therefore equivalent to 115 mg of sodium.)

No comments relating to the sodium warning or to sodium content labeling were received in response to the advance notice of proposed rulemaking. In the **Federal Register** of November 16, 1988 (53 FR 46024), FDA published the tentative final monograph for OTC internal analgesic, antipyretic, and antirheumatic drug products and included recommendations relating to sodium labeling similar to those recommended by the Panel. For those products containing 0.2 mEq (5 mg) or higher of sodium per dosage unit, the proposed labeling of the product contains the sodium content per dosage unit (e.g., tablet, teaspoonful). For those products containing more than 5 mEq (125 mg) of sodium in the maximum recommended daily dose, the proposed warning is as follows: "Do not take this product if you are on a sodium restricted diet unless directed by a doctor." (See 53 FR 46204 at 46256.) In response to one comment's request that professional labeling include the use of buffered aspirin for transient ischemic attacks, the agency excluded sodium-containing buffered aspirin because the chronic ingestion of sodium was thought to be ill-advised in such patients (see 53 FR 46024 at 46229). In response to a similar request for professional labeling of aspirin for myocardial infarction, the agency included the proposal along with a statement that the amount of sodium contained in buffered aspirin may not be tolerated by patients with active sodium-retaining states such as congestive heart or renal failure (see 53 FR 46204 at 46232).

The agency did not receive comments relating to sodium labeling in response to the tentative final monograph. However, OTC internal analgesic-antipyretic drug products currently marketed are not required to meet the proposed labeling requirements until a final monograph is published. Thus, any revisions to the previously proposed labeling would not adversely affect currently marketed drug products.

Reference

(1) Levy, A. S. and J. T. Heimbach, Division of Consumer Studies (HFF–240), Center for Food Safety and Applied Nutrition, Food and Drug Administration, "Recent Public Education Efforts About Health and Diet in the United States," Washington, DC 1989.

The Agency's Tentative Conclusions on Sodium Labeling for OTC Drug Products

FDA believes that the public interest in and the public health consequences of sodium intake have produced a need for more informative and consistent sodium content labeling information on drugs and foods. This is particularly true for individuals with hypertension or heart failure, who must monitor their sodium intake. The agency has considered a number of items in developing this proposal: (1) The existing labeling requirements for OTC antacid drug products, (2) the proposed sodium labeling requirements for OTC laxative and internal analgesic-antipyretic drug products, (3) the Panel's recommendations for OTC antidiarrheal drug products, (4) the final rule on sodium labeling for food products, and (5) other recent agency proposals on food labeling. Each rulemaking adequately conveys the necessary information, but a more uniform approach would be better understood and less confusing to consumers.

In order to establish uniform content declarations, warnings, and descriptive terms relating to sodium in foods and orally administered OTC drugs, the agency is proposing to adopt: (1) 5 mg or more as the amount of sodium per a single recommended dose of the product (which may involve one or more dosage units, e.g., tablets, teaspoonsful, etc.) that requires a sodium content declaration, (2) 140 mg (about 6 mEq) as the amount of sodium present in the maximum recommended daily dose for an orally administered OTC drug product above which a sodium warning is required, and (3) voluntary use of the following descriptive terms: "Sodium-free" for those OTC drug products containing less than 5 mg in the maximum recommended daily dose; "very low sodium" for those containing 35 mg or less; and "low sodium" for those containing 140 mg or less. These proposals should help provide uniformity in the sodium labeling of food and OTC drug products. The agency is therefore proposing to amend the general drug labeling provisions in 21 CFR part 201 to include the following provisions for OTC orally administered drug products: (1) A quantitative

labeling requirement for sodium content, (2) a warning for persons on sodium-restricted diets, and (3) the voluntary use of descriptive terms relating to quantitative sodium content.

Because consumers and health professionals are accustomed to computing sodium intake in mg (49 FR 15510 at 15530), and for uniformity in the declaration of sodium content labeling for foods and orally administered OTC drug products, the term "milligrams" or the abbreviation "mg" should be used to designate the sodium content of OTC drug products. To simplify OTC drug labeling and to make it more readable for consumers, the sodium content, in mg, should be rounded off to the nearest whole number when the dosage unit contains less than 5 mg of sodium, to the nearest 5 mg increment (5, 10, 15, etc.) when the dosage unit contains 5 to 140 mg, and to the nearest 10 mg increment (140, 150, etc.) when the dosage unit contains greater than 140 mg. Furthermore, the declaration of sodium content should include the total sodium in a dosage unit of the drug product, i.e., sodium from active and inactive ingredients.

The existing quantitative sodium labeling requirement for OTC antacid drug products is based on the sodium content per dosage unit. The existing regulation (21 CFR 331.30(f)) states that the labeling of the product contains the sodium content per dosage unit (e.g., tablet, teaspoonful) if it is "0.2 mEq. (5 mg) or higher." However, a single dose of an antacid product may consist of more than one dosage unit (e.g., 2 tablets per dose). Although a single dosage unit (e.g., one tablet, teaspoonful) may contain less than 5 mg sodium, a single dose of the drug may contain 5 mg or more of sodium. The agency believes that the existing quantitative sodium labeling requirement should be changed to state that the product's labeling shall contain the sodium labeling per dosage unit (e.g., tablet, teaspoonful) if the sodium content of a single recommended dose of the product (which may involve one or more dosage units) is 5 mg or more. Therefore, the agency is proposing in this notice that if the single recommended dose (one or more dosage units) of the product contains 5 mg or more of sodium, a declaration of sodium content expressed in mg per single dosage unit (e.g., tablet, teaspoonful) is required. This declaration of sodium content should be rounded off appropriately, as discussed above.

As an illustration, if a single dosage unit of a product contained 3.8 mg of sodium and the recommended dose of the product was one dosage unit, the product would not have to bear sodium content labeling. If the recommended dose of the same product was two dosage units, the product would need to bear sodium content labeling per dosage unit, and the amount would be rounded off to 4 mg (the nearest whole number). If the recommended dose of the product was one or two dosage units, the product would have to bear sodium content labeling because the consumer would have the option to take a two-dosage-unit dose. If a single dosage unit of the product contained 7.6 mg of sodium, the labeling would be rounded off to 10 mg (the nearest 5 mg increment). If a single dosage unit of the product contained 146 mg, it would be rounded off to 150 mg (the nearest 10 mg increment).

A warning would also be required on OTC drug products containing more than 140 mg sodium in the maximum recommended daily dose to alert persons who are on a sodium-restricted diet. The agency is proposing in this document that the sodium warning currently required by the final monograph for OTC antacid drug products ("Do not use this product except under the advice and supervision of a physician if you are on a sodium restricted diet") be revised slightly to reflect the current format and style of recently published OTC drug tentative final and final monographs. The revised warning would read: "Do not use this product if you are on a sodium restricted diet unless directed by a" (select one of the following "physician" or "doctor").

This proposed rule would also allow the use, in certain cases, of the descriptive terms "sodium free," "very low sodium," or "low sodium." These descriptive terms for OTC drug products are the same as those discussed above for foods having the corresponding sodium content in one serving. The agency believes that consumers are already familiar with the terms as used in food labeling. However, the sodium content of food per serving cannot reasonably be equated to the sodium content of a drug dosage unit. A dose of a drug may consist of multiple dosage units, and the maximum dose per day could involve multiple doses. The agency is therefore proposing for any orally administered OTC drug product containing sodium that the basis for determining which descriptor ("sodium free," "very low sodium," or "low sodium") should be used is the amount of sodium contained in the maximum recommended daily dose.

The proposed warning in the tentative final monograph for OTC laxative drug products used the term "salt" rather than the term "sodium" as used in § 331.30(c)(5) of the final monograph for OTC antacid drug products. In discussing diet, the term "salt" generally refers to sodium chloride, which is the commonly used table "salt." However, the term salt is not synonymous with sodium because some compounds that are salts do not contain sodium. Sodium chloride is a primary source of dietary sodium consumption, but there are other sources of dietary sodium such as sodium bicarbonate (baking soda) and monosodium glutamate (MSG). Similarly, drugs may also contain sodium in the form of sodium chloride, sodium bicarbonate, or other sodium ingredients. The term "salt" in the warning proposed in the tentative final monograph for OTC laxative drug products does not specifically refer to sodium. The agency believes that the warning referring to "sodium" in the final monograph for OTC antacid drug products is more appropriate. The agency has included in this proposed rule a provision that the term "salt" should not be used interchangeably or substituted for the term "sodium."

In an effort to simplify OTC drug labeling, the agency proposed in a number of tentative final monographs to substitute the word "doctor" for "physician" in OTC drug monographs on the basis that the word "doctor" is more commonly used and better understood by consumers. Based on comments received to these proposals, the agency has determined that final monographs and any applicable OTC drug regulations will give manufacturers the option of using either the word "physician" or the word "doctor." This proposed rule includes that option.

The agency encourages manufacturers to comply voluntarily with the provisions of this proposed rule despite the fact that revisions in the requirements may occur in the final rule in response to submitted comments. Should any manufacturer choose to adopt the labeling described in this proposed rule, and should any revisions occur in the final rule, the agency will permit the use of existing stocks of labels for those products labeled according to the proposed rule for a period of 1 year following publication of the final rule.

Should this proposed amendment to part 201 relating to the sodium labeling of all OTC orally administered drug products be published as a final rule, then the existing requirements relating to sodium labeling in § 331.30 (c)(5) and (f) of the final monograph for OTC antacid drug products and the proposed

sodium labeling requirements being considered in other ongoing OTC drug rulemaking will be deleted.

The agency has examined the economic consequences of this proposed rulemaking and has determined that it does not require either a regulatory impact analysis, as specified in Executive Order 12291, or a regulatory flexibility analysis, as defined in the Regulatory Flexibility Act (Pub. L. 96–354).

Should this proposed rule become a final rule, one-time label modification costs associated with changing product labels would be incurred by some manufacturers. FDA estimates those costs to total less than $500,000 for the entire industry. This projected cost is based on estimates of the number of products that will be affected by the proposed rule, the number of distinct label changes that will be required, and the cost of printing new labels.

OTC antacid drug products are the primary products having a significant number of orally administered active ingredients containing sodium. The monograph for those products has been in effect since 1974 and these products currently bear sodium labeling. For these products, the labeling change would involve a slight change in wording, resulting only in a minor cost to have a labeling revision printed. In almost all cases, this revision would be routinely done at the next labeling printing so that minimal costs should be incurred. Manufacturers will have up to 12 months after publication of a final rule in the **Federal Register** to revise their product labeling. It is anticipated that most antacid drug products would undergo a label printing within a 12-month period. Because these products already bear sodium labeling warnings, the agency would be willing to extend the time period beyond 12 months, if necessary, upon request, for the revised wording to be implemented.

Other OTC drug products (i.e., laxatives and internal analgesics) having a few sodium-containing active ingredients that would be affected by mandatory sodium labeling currently are not required to bear sodium labeling. These products would need to have new labels printed to incorporate the sodium labeling. These products will also need to have new labeling printed in the future when the final monographs for OTC laxative and internal analgesic drug products are published. This again involves one-time label modification costs. For products that will be undergoing such labeling changes, the incremental costs attributable to this rule for sodium labeling would be negligible. A limited number of OTC laxative and internal analgesic drug products contain sodium-containing active ingredients. Tentative final monographs have been published that proposed sodium labeling requirements for these products, and no adverse economic comments have been received in response to the proposals.

The agency is not aware of any significant number of other OTC drug products that would be affected due to the sodium content of inactive ingredients. The use of the sodium descriptive terms proposed in this rulemaking is voluntary. Therefore, any implementation of these terms could be done by a manufacturer at any time that new labeling is ordered. The agency finds that the cost of adding one of these descriptive terms to the product's labeling would be negligible.

Therefore, the agency concludes that the economic impact of this proposed rule, if implemented, would be minimal and that the proposed rule is not a major rule as defined in Executive Order 12291. Further, the agency certifies that the proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on orally administered OTC drug products. Types of impact may include, but are not limited to, costs associated with relabeling, repackaging, or reformulating. Comments regarding the impact of this rulemaking on orally administered OTC drug products should be accompanied by appropriate documentation. A period of 60 days from the date of publication of this proposed rulemaking in the **Federal Register** will be provided for comments on this subject to be developed and submitted. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

The agency has determined under 21 CFR 25.24(c)(6) 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.

Interested persons may, on or before June 24, 1991, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments, objections, or requests for oral hearing before the Commissioner on the proposed amendment. A request for an oral hearing must specify points to be covered and time requested. Written comments on the agency's economic impact determination may be submitted on or before June 24, 1991. Three copies of all comments, objections, and requests are to be submitted, except that individuals may submit one copy. Comments, objections, and requests are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Comments, objections, and requests may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Any scheduled oral hearing will be announced in the **Federal Register**.

List of Subjects

21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 331

Antacid drug products, Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act, it is proposed that subchapter C and D of chapter I of title 21 of the Code of Federal Regulations be amended in parts 201 and 331, respectively, as follows:

PART 201—LABELING

1. The authority citation for 21 CFR part 201 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 508, 510, 512, 701, 704, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 358, 360, 360b, 371, 374, 376); secs. 215, 301, 351, 354–360F, 361 of the Public Health Service Act (42 U.S.C. 216, 241, 262, 263b–263n, 264).

2. Section 201.64 is added to subpart C to read as follows:

§ 201.64 Sodium labeling.

(a) The labeling of orally administered over-the-counter (OTC) drug products shall contain the sodium content per dosage unit (e.g., tablet, teaspoonful) if the sodium content of a single recommended dose of the product (which may be one or more dosage units) is 5 milligrams or more.

(b) The sodium content shall be expressed in milligrams per dosage unit and shall include the total amount of sodium regardless of the source, i.e., from both active and inactive ingredients. The sodium content shall be rounded off to the nearest whole number when the dosage unit contains less than 5 milligrams, to the nearest 5 milligram

increment (5, 10, 15, etc.) when the dosage unit contains 5 to 140 milligrams, and to the nearest 10 milligram increment (140, 150, etc.) when the dosage unit contains greater than 140 milligrams.

(c) The labeling of all orally administered OTC drug products shall contain the following warning under the heading "Warning" (or "Warnings" if it appears with additional warning statements) if the amount of sodium present in the maximum recommended daily dose of the product is more than 140 milligrams: "Do not use this product if you are on a sodium restricted diet unless directed by a" (select one of the following: "Physician" or "doctor").

(d) The term "sodium free" may be used in the labeling of orally administered OTC drug products if the amount of sodium in the maximum recommended daily dose is less than 5 milligrams. For example, a product containing 4 milligrams sodium per tablet with directions to take one tablet daily may use the term "sodium free" in its labeling. However, when the recommended dose in an OTC drug monograph provides for the taking of more than one dosage unit per day, e.g., take one or two tablets, or take two tablets, the same product containing 4 milligrams sodium per tablet shall not use the term "sodium free" because the maximum recommeded daily dose contains 8 milligrams sodium.

(e) The term "very low sodium" may be used in the labeling of orally administered OTC drug produts if the amount of sodium in the maximum recommended daily dose is 35 milligrams or less.

(f) The term "low sodium" may be used in the labeling of orally administered OTC drug products if the amount of sodium in the maximum recommeded daily dose is 140 milligrams or less.

(g) The term "salt" is not synonymous with the term sodium and shall not be used interchangeably or substituted for the term "sodium."

PART 331—ANTACID PRODUCTS FOR OVER-THE-COUNTER (OTC) HUMAN USE

3. The authority citation for 21 CFR Part 331 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

§ 331.30 [Amended]

4. Section 331.30 *Labeling of antacid products* is amended in Subpart D by removing paragraph (c)(5) and redesignating paragraphs (c)(6) and (c)(7) as paragraphs (c)(5) and (c)(6), respectively, and by removing paragraph (f) and redesignating paragraph (g) as paragraph (f).

Dated: March 19, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

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