DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR Parts 331 and 332

[Docket No. 85N-0093]

Antacid and Antiflatulent Drug Products for Over-the-Counter Human Use; Amendment of the Monographs

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to amend the monographs for over-the-counter (OTC) antacid and antiflatulent drug products by adding new sections that will exempt certain antacid, antiflatulent, and antacid/antiflatulent combination drug products from that part of the accidental overdose warning required by § 330.1(g) (21 CFR 330.1(g)) that states, "In case of accidental overdose, seek professional assistance or contact a poison control center immediately." The exemption from the warning above is being provided because certain antacid and antiflatulent active ingredients contained in OTC drug products have been determined to have a low potential for acute toxicity resulting from accidental ingestion. FDA is issuing this final rule after considering public comment on the agency's proposed regulation and all new data and information on OTC antacid and antiflatulent drug products that have come to the agency's attention. This final rule is part of the ongoing review of OTC drug products conducted by FDA.

EFFECTIVE DATE: August 1, 1986.

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

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 4, 1974 (39 FR 19862), FDA issued a final monograph for OTC antacid drug products (21 CFR Part 331) and a final monograph for OTC antiflatulent drug products (21 CFR Part 332) that established conditions under which these drug products are generally recognized as safe and effective and not misbranded. At that time, FDA exempted sodium bicarbonate powder from the general accidental overdose warning required by § 330.1(g) (39 FR 19867). Since publication of the antacid final monograph, a number of firms have petitioned for an exemption from the general overdose warning required on the labeling of antacid, antiflatulent, and antacid/antiflatulent combination drug products.

In the **Federal Register** of April 13, 1984 (49 FR 14908), FDA issued a notice of proposed rulemaking to exempt certain antacid, antiflatulent, and antacid/antiflatulent combination drug products from the accidental overdose warning statement required by § 330.1(g), i.e., "In case of accidental overdose, seek professional assistance or contact a poison control center immediately." FDA proposed this exemption from the warning because certain antacid and antiflatulent active ingredients in OTC drug products have been demonstrated to have a low potential for acute toxicity resulting from accidental ingestion. The labeling of products containing these ingredients would continue to contain the first part of the warning required by § 330.1(g) which states, "Keep this and all drugs out of the reach of children." This requirement would have applied to sodium bicarbonate as well as to other antacid and antiflatulent drug products.

Interested persons were invited to file by June 12, 1984, written comments regarding the proposal. Interested persons were invited to file comments on the agency's economic impact determination by August 13, 1984. Final agency action occurs with the publication of this final rule.

In response to the proposed rule, one manufacturer of sodium bicarbonate products submitted a comment. Copies of the comment received are on public display in the Dockets Management Branch.

The comment objected to the proposed rule because it appears to take away an exemption from the requirements of § 330.1(g) that is currently allowed for products containing sodium bicarbonate. The comment stated that the antacid final rule published in the **Federal Register** of June 4, 1974 (39 FR 19867) provided an exemption to sodium bicarbonate from the labeling requirements of § 330.1(g), and that the exemption applies to both the "keep out of reach of children" and the accidental overdose portions of the warning. The comment objected that the proposed rule would remove the existing exemption which sodium bicarbonate has from the "keep out of reach of children" statement without following necessary administrative procedures. The comment argued that there is no factual need for the "keep out of reach of children" warning on sodium bicarbonate products because there have been no instances of a child voluntarily ingesting these products and becoming ill even though the products have been promoted for uses directly involving children. The comment also argued that requiring the warning on sodium bicarbonate products could undermine the effectiveness of warning statements on other products because consumers know that sodium bicarbonate is safe and would ignore the warning and may assume that other product warnings in general are also unjustified and unimportant. The comment concluded that it had no objection to FDA's stated purpose for the proposed rule, but requested that FDA remove the implied revocation of the exemption for sodium bicarbonate products from having to bear the warning "Keep this and all drugs out of the reach of children."

After considering the comment's arguments, the agency agrees that sodium bicarbonate powder, when packaged and promoted primarily for other than drug uses, e.g., baking ingredient, refrigerator deodorant, household cleanser, etc., does not pose a threat to small children. The inclusion of the "keep out of reach of children" warning on such products would be unnecessary and may be unduly alarming to consumers who have routinely used these products around children. Therefore, the agency concludes that sodium bicarbonate products, in powder form and intended primarily for other than drug uses, may be exempt from both the "keep out of reach of children" and the accidental overdose warnings required by § 330.1(g). However, because the agency believes it is generally best to keep any drug product out of the reach of children, regardless of its potential for causing acute toxicity, the labeling of sodium bicarbonate products marketed primarily as a drug and all other antacid and antiflatulent drug products must continue to contain the first part of the warning which states "Keep this and all drugs out of the reach of children."

Accordingly, the agency is adding new §§ 331.30(g) and 332.30(c) that will exempt antacid drug products identified in § 331.11(a), (b), and (d) through (m) and antiflatulent drug products identified in § 332.10 or any allowable combination of these ingredients to be exempt from the general overdose warning requirement in § 330.1(g). With the exception of sodium bicarbonate when marketed in a powder form and intended primarily for other than drug uses, the labeling of OTC antacid and antiflatulent drug products containing these ingredients must continue to contain the first part of the warning which states, "Keep this and all drugs out of the reach of children." Because no new data were submitted regarding t' toxicity of bismuth compounds, the labeling of products containing these

ingredients, identified in § 331.11(c), must continue to bear both warnings required by § 330.1(g).

Because this final rule relates only to warnings for OTC antacid and antiflatulent drug products, the changes in the "exclusivity" policy that were recently published in the **Federal Register** of May 1, 1986 (51 FR 16258) do not apply to this document.

One comment was submitted in response to the agency's request for specific comment on the economic impact of this rulemaking (49 FR 14909). The comment argued that marketers of sodium bicarbonate products would suffer unjustifiable, irreparable economic harm if sodium bicarbonate products were required to bear the "keep out of reach of children" statement because the statement would deter consumers from purchasing the product for use as a refrigerator deodorant, baking ingredient, etc. Because this final rule exempts powder forms of sodium bicarbonate intended primarily for other than drug uses from the "keep out of reach of children" statement, the comment's concern is moot. The agency has examined the economic consequences of this final rule in conjunction with other rules resulting from the OTC drug review. In a notice published in the **Federal Register** of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this final rule for OTC antacid and antiflatulent drug products, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act, Public Law 96–354. That assessment included a discretionary Regulatory Flexibility Analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC antacid and antiflatulent drug products is not expected to pose such an impact on small businesses. Therefore, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

List of Subjects

21 CFR Part 331

Labeling, OTC drugs, Antacid drug products.

21 CFR Part 332

Labeling, OTC drugs, Antiflatulent drug products.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act, Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations is amended in Parts 331 and 332 as follows:

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

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

Authority: Secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371); 5 U.S.C. 553; 21 CFR 5.11.

§ 331.11 [Amended]

2. In Part 331, § 331.11 *Listing of specific active ingredients* is amended in paragraph (k)(1) by revising the last sentence to read:

* * * * *

(k) * * *

(1) * * * That part of the warning required by § 330.1(g), which states, "Keep this and all drugs out of the reach of children" is not required on a product which contains only sodium bicarbonate powder and which is intended primarily for other than drug uses.

3. In Part 331, § 331.30 is amended by adding new paragraph (g) to read as follows:

§ 331.30 Labeling of antacid products.

* * * * *

(g) *Exemption from the general accidental overdose warning.* The labeling for antacid drug products containing the active ingredients identified in § 331.11(a), (b), and (d) through (m); permitted combinations of these ingredients provided for in § 331.10; and any of these ingredients or combinations of these ingredients in combination with simethicone (identified in § 332.10 of this chapter and provided for in § 331.15(c)), are exempt from the requirement in § 300.1(g) of this chapter that the labeling bear the general warning statement "In case of accidental overdose, seek professional assistance or contact a poison control center immediately." With the exception of sodium bicarbonate powder products identified in § 331.11(k)(1), the labeling must continue to bear the first part of the general warning in § 330.1(g) of this chapter, which states, "Keep this and all drugs out of the reach of children."

PART 332—ANTIFLATULENT PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

4. The authority citation for 21 CFR Part 332 continues to read as follows:

Authority: Secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371); 5 U.S.C. 553; 21 CFR 5.11.

5. In Part 332, § 332.30 is amended by adding new paragraph (c) to read as follows:

§ 332.30 Labeling of antiflatulent products.

* * * * *

(c) *Exemption from the general accidental overdose warning.* The labeling for antiflatulent drug products containing simethicone identified in § 332.10 and antacid/antiflatulent combination drug products provided for in § 332.15, containing the active ingredients identified in § 331.11(a), (b), and (d) through (m) of this chapter are exempt from the requirement in § 330.1(g) of this chapter that the labeling bear the general warning statement "In case of accidental overdose, seek professional assistance or contact a poison control center immediately." The labeling must continue to bear the first part of the general warning in § 330.1(g) of this chapter, which states, "Keep this and all drugs out of the reach of children."

Dated: May 3, 1986.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 86–17181 Filed 7–31–86; 8:45 am]

BILLING CODE 4160–01–M