F. Model Health Claims

In proposed § 101.80(e), FDA is providing model health claims to illustrate the requirements of new § 101.80. FDA emphasizes that these model health claims are illustrative only. If the agency authorizes claims about the relationship between sugar alcohols and dental caries, manufacturers will be free to design their own claim so long as it is consistent with § 101.80(c).

VII. Environmental Impact

The agency has determined under 21 CFR 25.24 (a)(11) 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.

VIII. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because it enables firms to make claims that they would otherwise be prohibited from making, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

IX. Effective Date

FDA is proposing to make these regulations effective 30 days after the publication of a final rule based on this proposal.

X. Comments

Interested persons may, on or before October 3, 1995, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, 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.

XI. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a. m. and 4 p. m., Monday through Friday.

1. Drozen, Melvin S., ''Health claim petition regarding the noncariogenicity of sugar alcohols,'' August 31, 1994.

2. Drozen, Melvin S., ''Objections and request for a hearing by Working Group of sugar alcohol manufacturers to the revocation of 21 C.F.R. section 105.66(f),'' Docket No. 91N–384L, Dockets Management Branch, FDA, Rockville, MD.

3. Saltsman, Joyce J., CFSAN, FDA, Letter to Melvin S. Drozen, September 15, 1994.

4. Saltsman, Joyce J., CFSAN, FDA, Letter to Melvin S. Drozen, October 7, 1994.

5. Drozen, Melvin S., Letter to FDA, November 15, 1994.

6. Saltsman, Joyce J., CFSAN, FDA, Memorandum of telephone conversation, December 8, 1994.

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9. Ten Cate, J. M., ''Demineralization models: Mechanistic aspects of the caries process with special emphasis on the possible role of foods,'' *Journal of Dental Research,* 65 (Special Issue):1511–1515, 1986.

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16. LSRO, FASEB, ''Dietary Sugars in Health and Disease, IV. Mannitol,'' Bethesda, MD, July, 1978.

17. Working Group Consensus Report, ''Animal caries,'' *Journal of Dental Research,* 65:1528–1529, 1986.

18. Working Group Consensus Report, ''Human plaque acidity,'' *Journal of Dental Research,* 65:1530–1531, 1986.

19. Working Group Consensus Report, ''Demineralization/remineralization,'' *Journal of Dental Research,* 65:1532–1536, 1986.

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22. Kandelman, D., and G. Gagnon, ''Clinical results after 12 months from a study of the incidence and progression of dental caries in relation to consumption of chewing-gum containing xylitol in school preventive programs,'' *Journal of Dental Research,* 66:1407–1411, 1987.

23. Rekola, M., ''Changes in buccal white spots during two-year total substitution of dietary sucrose with xylitol,'' *Acta Odontologica Scandinavica,* 44:285–290, 1986.

24. Mäkinen, K. K., and A. Scheinin, ''Turku sugar studies. VI. The administration of the trial and the control of the dietary regimen,'' *Acta Odontologica Scandanavia,* 33:105–127, 1975.

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