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December 16, 1999

Dockets Management Branch (HFA-305) Food and Drug Administration Department of Health and Human Services Room 1061 5630 Fishers Lane Rockville, Maryland 20852

Re: <u>Docket No. 94P-0036 (*Trans* Fatty Acids) -- Reauest For Extension Of Comment Period</u>

Dear Food and Drug Administration:

The Chocolate Manufacturers Association (CMA) and the National Confectioners Association (NCA) request that the Food and Drug Administration (FDA) extend the comment period in *the trans* fatty acid rulemaking by at least 60 days. CMA and NCA are national, not-for-profit trade associations representing the majority of manufacturers of chocolate and confectionery in the United States. CMA and NCA members produce over 90% of all chocolate and confectionery consumed in this country.

As a threshold matter, CMA and NCA believe that 90 days is too short a time period for them to survey their members and develop well-reasoned comments on the labeling of *trans* fatty acid, which involves complex scientific, regulatory, and economic issues. Moreover, the comment period includes the end of year holiday season, during which many individuals will take long-planned vacations and, therefore, will not be available to work on responding to FDA's proposal.

As FDA recognized in the rulemaking preamble, the proposed requirements, if finalized, would affect many thousands of confectionery products. Affected confectionery manufacturers need time to evaluate their options for responding to FDA's proposed labeling requirements. Many firms will want to test their products to determine whether they contain 0.5 g or more *trans* fat per serving. Such testing is time consuming. It may also be necessary to investigate appropriate analytical methods for measuring *trans* fatty acids in confectionery products. Assuming a firm will be affected in a more-than-insignificant way by the proposed requirements, it may want to evaluate options such as product reformulation with alternative fat and oil sources that

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contain lower amounts of *trans* fatty acids. Until a confectionery firm knows the extent to which FDA's proposed requirements will affect its specific products, it may not be possible for that firm to provide meaningful input to CMA and NCA to assist the associations in developing an industry position.

The sequential events discussed in the prior paragraph are time consuming and cannot, as a practical matter, be completed within the 90-day comment period. The difficulty of commenting within the 90-day comment period is exacerbated by the fact that, as FDA recognized in the rulemaking preamble, a large number of confectionery firms are small businesses. These small firms typically do not have the resources or inhouse staff that would enable them to respond quickly to CMA's and NCA's request for information, so that CMA and NCA can develop comments that truly reflect the industry position.

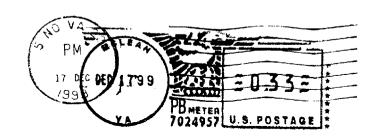
For these reasons, CMA and NCA respectfully request that the comment period be extended by at least 60 days. CMA and NCA appreciate the agency's attention to this request.

Respectfully submitted,

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President

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