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September 16, 2003

Dockets Management Branch  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061 (HFA-305)  
Rockville, MD 20852

Re: Request for Extension of Comment Period - Milk and Cream Products and Yogurt Products; Petition to Revoke Standards for Lowfat Yogurt and Nonfat Yogurt and to Amend Standards for Yogurt and Cultured Milk (Docket No. 00P-0685)

Dear Sir or Madam:

On behalf of the National Yogurt Association ("NYA"), we respectfully request that the comment period for the above-captioned Advance Notice of Proposed Rulemaking ("ANPR") be extended for a period of 90-days until and including December 30, 2003. As further explained herein, the additional time is necessary to compile comprehensive comments that address scientific and other issues including those raised by the Food and Drug Administration ("FDA" or "Agency"). NYA's comments will provide significant information to assist the Agency in developing sound public policy.

**I. Request for Extension of Time and Proposal Involved**

Pursuant to 21 C.F.R. § 10.40(b)(3), NYA respectfully requests a 90-day extension of the comment period for the Milk and Cream Products and Yogurt Products; Petition to Revoke Standards for Lowfat Yogurt and Nonfat Yogurt and to Amend Standards for Yogurt and Cultured Milk ANPR (hereinafter referred to as the "Yogurt Standard ANPR"). The Yogurt Standard ANPR was published in the Federal Register of July 3, 2003, and provided that comments be submitted by October 1, 2003.<sup>1</sup> NYA's request for an additional 90-days would allow for comments to be submitted by December 30, 2003.

<sup>1</sup> 68 Fed. Reg. 39873 (July 3, 2003).

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## II. Statement of Grounds

NYA is the national nonprofit trade association representing the manufacturers and marketers of live and active culture yogurt products as well as suppliers to the yogurt industry. NYA's member companies are among the largest yogurt manufacturers in the U.S., as well as nationally recognized retailers. NYA sponsors scientific research regarding the health benefits associated with the consumption of live and active culture yogurt and serves as an information resource for the American public about these attributes.

NYA has aggressively pursued the Agency to resolve the numerous outstanding issues that have existed since the original yogurt standards of identity were published on January 30, 1981.<sup>2</sup> At the time the original standards were finalized, companies raised many objections to the new requirements and, in an attempt to address their concerns, FDA amended and stayed various provisions.<sup>3</sup> However, FDA's actions resulted in yogurt standards of identity that are fragmented and incoherent and that remain incomplete. Additionally, unlike other dairy products, the yogurt standards do not conform to the general provisions of the Nutrition Labeling and Education Act ("NLEA").<sup>4</sup> Due to these severe deficiencies and other issues associated with the existing standards of identity for full fat, lowfat, and nonfat yogurt, NYA filed a Citizen Petition on February 18, 2000 to prompt action by the Agency.

FDA recognized that NYA's Citizen Petition raised meritorious issues and published the Yogurt Standard ANPR.<sup>5</sup> Clearly, NYA has a strong interest in the rulemaking for the yogurt standards. Since the publication of the Yogurt Standard ANPR, NYA has been diligently compiling information to update its position on the proposed provisions as well as address the various questions for which the Agency has requested comments. Also, the Yogurt Standard ANPR is the first opportunity for many within the relevant industries to comment on issues that have been pending for over 20-years. It has become

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<sup>2</sup> 46 Fed. Reg. 9924 (January 30, 1981).

<sup>3</sup> 41 Fed. Reg. 41519 (September 21, 1982).

<sup>4</sup> 60 Fed. Reg. 56541 (November 9, 1995).

<sup>5</sup> 68 Fed. Reg. 39873 (July 3, 2003).

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apparent through discussions with its members and other stakeholders that additional time is required to provide them with an opportunity to contribute meaningful input and endeavor to reach consensus so that comprehensive comments may be developed.

NYA has greatly anticipated a response from the Agency about its Citizen Petition. NYA believes that an extension of time for 90-days is sufficient to produce comments that adequately address the issues in the Yogurt Standard ANPR. Moreover, the FDA benefits from complete and thorough information that considers all of the pertinent issues and significant stakeholders as NYA's comments will assist the Agency in developing sound public policy.

If there are any questions or if additional information is required, please do not hesitate to contact us.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Leslie G. Sarasin". The signature is written in a cursive style with a large initial "L".

Leslie G. Sarasin  
President  
National Yogurt Association