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July 21, 2003

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

**Re: Comments to Withdrawal of Certain Proposed Rules and Other
 Proposed Action, Notice of Intent (Docket No. 02N-0434)**

Dear Sir or Madam:

On behalf of the National Yogurt Association ("NYA"), we are submitting comments to the Notice of Intent to Withdraw Certain Proposed Rules and Other Proposed Actions (Docket No. 02N-0434) that was published in the *Federal Register* of April 22, 2003.¹ Specifically, the Food and Drug Administration ("FDA" or "Agency") identified the Advanced Notice of Proposed Rulemaking for Yogurt Products, Frozen Yogurt, Frozen Lowfat Yogurt, and Frozen Nonfat Yogurt; Petition to Establish Standards of Identity and to amend the Existing Standards (hereinafter referred to as the "1991 Yogurt ANPR") as a proposed rule that should be withdrawn.

NYA fully agrees with the Agency regarding the withdrawal of the 1991 Yogurt ANPR. As will be discussed further in these comments, the withdrawal of the 1991 Yogurt ANPR allows the Agency to address comprehensively the numerous outstanding issues that currently plague the existing yogurt standards. The publication of Advanced Notice of Proposed Rulemaking for 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.² (hereinafter referred to as the "2003 Yogurt Standard ANPR") provides the proper forum for FDA to begin informal rulemaking procedures to replace the existing yogurt standards of identity.

¹ 68 Fed. Reg. 19766 (April 22, 2003).

² 68 Fed. Reg. 39873 (July 3, 2003).

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I. BACKGROUND – FDA ACTIONS ON THE YOGURT STANDARDS OF IDENTITY

On January 30, 1981, FDA published a final rule for the three yogurt standards of identity.³ The standards established definitions for yogurt, lowfat yogurt, and nonfat yogurt, and contained provisions regarding optional dairy ingredients, other optional ingredients, methods of analysis, nomenclature, and label declarations. However, due to objections FDA received requesting hearings on certain provisions of the final rule, FDA amended some provisions, and stayed other provisions pending hearings, which has resulted in fragmented standards of identity for yogurt products.⁴

On November 9, 1995, FDA proposed to revoke the standards of identity for several lowfat and nonfat dairy products, including lowfat yogurt and nonfat yogurt.⁵ By removing these standards, manufacturers would still be able to name the products in accordance with the general provisions of the Nutrition Labeling and Education Act (“NLEA”) so long as the product is not nutritionally inferior to the standard form.⁶ Because lowfat and nonfat yogurts contain less vitamin A than full fat yogurt, under the proposed rule, lowfat and nonfat yogurts would require vitamin A fortification to meet the level of full fat yogurt.

In the final rule, FDA acknowledged that yogurt differs from other dairy products and agreed with industry that the rule would result in significant relabeling, reformulation, and equipment costs for yogurt manufacturers. FDA recognized that effective standards for yogurts that are not full fat already exist. Thus, FDA deferred action on its proposal to revoke the lowfat and nonfat yogurt standards.

As a result of this history of incomplete regulatory actions by FDA, the yogurt standards of identity have remained fragmented and incoherent twenty years after they were finalized. Currently, the yogurt standards exist as an incomplete and unclear assortment of effective and stayed provisions, which provides little guidance to industry.

³ 46 Fed. Reg. 9924 (January 30, 1981).

⁴ 47 Fed. Reg. at 41519.

⁵ 60 Fed. Reg. 56541 (November 9, 1995).

⁶ §130.10(b).

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II. THE 2003 YOGURT STANDARD ANPR IS THE PROPER FORUM TO ADDRESS THE EXISTING YOGURT STANDARDS OF IDENTITY.

Only recently has FDA taken step to resolve the numerous pending issues associated with the standards of identity for yogurt. As you know, on February 18, 2000, NYA submitted a Citizen Petition (Docket No. 00P-0685) requesting FDA to revoke the existing standards of identity and replace it with proposed standards that were included in the petition. NYA represents the major yogurt manufacturers in the U.S. and the Citizen Petition provides meaningful contributions from these companies to address the numerous pending issues of the existing standards of identity.

On April 22, 2003, FDA published the Notice of Intent to Withdraw Certain Proposed Rules and Other Proposed Actions.⁷ FDA stated that it would no longer be appropriate to address these proposed rules due to the extended period of time that has elapsed since their publication and that the comments may have become outdated. Among the proposed rules to be withdrawn, FDA identified the 1991 Yogurt ANPR.

NYA completely agrees with the withdrawal of the 1991 document. The 1991 Yogurt ANPR is not germane to the issues relating to the yogurt standards of identity and raises only a fraction of the concerns with the yogurt standards. Other more substantial issues have been raised with the Agency since the time the yogurt standards of identity were finalized in 1981. The single issue raised by the 1991 Yogurt ANPR that relates to the yogurt standards of identity is the use of safe and suitable sweeteners, which is also addressed in the NYA Citizen Petition and the 2003 Yogurt Standard ANPR.

FDA has acknowledged that NYA's Citizen Petition raises meritorious issues regarding the yogurt standards of identity. Accordingly, FDA published the Yogurt Standard ANPR, which provides the proper forum for addressing the existing yogurt standards of identity. Comments may be submitted addressing specific issues raised by NYA's Citizen Petition such as consumer expectation that yogurt products contain a minimum level of live and active cultures and that this expectation should be accurately reflected in the standard. Also, this proposed rule allows FDA to begin the informal rulemaking process to replace the existing yogurt standards of identity with those proposed standards set forth in NYA's Citizen Petition.

⁷ 68 Fed. Reg. 19766 (April 23, 2003).

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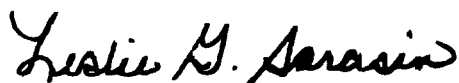
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Therefore, it is appropriate for FDA to withdraw the 1991 Yogurt ANPR so that the Agency may deal comprehensively with yogurt standards of identity through the rulemaking process initiated by the publication of the 2003 Yogurt Standard ANPR. NYA will be submitting comments to the 2003 Yogurt Standards ANPR. Also, NYA is hopeful that FDA will address the yogurt standards of identity in a timely manner as many issues have been pending for over twenty (20) years.

If we may be of assistance or if additional information is required, please do not hesitate to contact us.

Respectfully submitted,



Leslie Sarasin
President
National Yogurt Association