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COURIER

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 Actions; Notice of Intent (Docket No. 02N-0434)

Dear Sir or Madam:

On behalf of the National Soft Drink Association ("NSDA"), we are submitting these comments to the Notice of Intent to Withdraw Certain Proposed Rules and Other Proposed Actions, published in the *Federal Register* of April 22, 2003.[1]

The National Soft Drink Association (NSDA) is the national trade organization of the beverage industry. NSDA's member companies produce 95 percent of all soft drinks consumed annually in the United States. NSDA member companies also produce and distribute purified water, ready-to-drink teas, sports drinks, juice and juice-based beverages and other carbonated and non-carbonated products. In addition, the vast majority of the beverage licensors who manufacture concentrates and/or syrups from which soft drinks and other beverages are made belong to the Association. It is on behalf of these members that we submit these comments.

In particular, NSDA opposes the withdrawal of two proposed rules: (1) Caffeine in Nonalcoholic Carbonated Beverages (hereinafter referred to as the "Caffeine Proposed Rule"); and (2) Food Labeling; Declaration of Ingredients Common or Usual Name Declaration for Protein Hydrolysates and Vegetable Broth in Canned Tuna; "and/or" Labeling for Soft Drinks (hereinafter referred to as the "Food Labeling Proposed Rule").

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

02N-0434 CH

NSDA strongly disagrees with the tentative conclusion of the Food and Drug Administration ("FDA" or the "Agency") to withdraw the Caffeine and Food Labeling Proposed Rules. Although NSDA recognizes the importance of reevaluating the regulations process and removing proposed rulemakings that are no longer useful or valid, such is not the case with the Caffeine and Food Labeling Proposed Rules. These proposed rules memorialize the development of the Agency's policy on these issues and are the sole source of reference on these matters. To withdraw the proposed rules may unintentionally raise questions about longstanding practices within the soft drink industry to which the FDA has not objected. The withdrawal of the Caffeine and Food Labeling Proposals could well cause state regulators and the regulatory agencies of other countries to conclude that FDA's position on the matters addressed in the rulemakings has changed. NSDA does not believe that it is appropriate for the FDA to alter settled understandings of the regulatory status of caffeine or the use of and/or labeling for nutritive sweeteners in soft drinks inadvertently through a "housekeeping" process. NSDA recognizes that the FDA has limited resources and other more pressing public concerns, which have prevented the agency from completing the Caffeine and Food Labeling Rulemakings. However, the laudable goal of "cleaning house" should not be used to create unnecessary uncertainty and confusion.

I. COMMENTS TO THE WITHDRAWAL OF THE CAFFEINE PROPOSED RULE

A. Background – Regulatory History of Caffeine

Prior to the Caffeine proposal in 1987, there was considerable controversy and confusion about the regulatory status of the use of caffeine in carbonated beverages. At the time the Food Additives Amendment of 1958[2] was enacted, the FDA established lists of substances that it considered Generally Recognized As Safe ("GRAS") or prior sanctioned.[3] Caffeine was included among the ingredients and codified as a GRAS food additive in cola-type beverages.[4] As more data became available, FDA initiated a

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[2] Pub. L. 85-929, 72 Stat. 1784-1789.

[3] See 24 Fed. Reg. 9368 (November 20, 1959).

comprehensive review of food ingredients that it previously determined to be GRAS. This program became commonly referred to as the "GRAS Review."

As part of the GRAS Review, data on caffeine were compiled on its consumption, biological properties (e.g., mutagenicity, teratogenicity, carcinogenicity), and long-term effects. The expert committee convened for the specific purpose of the GRAS review determined that uncertainties existed about caffeine that requires additional studies. Also, the FDA searched its files for documents relating to the possibility of caffeine's regulatory status as a prior sanctioned ingredient. The Agency acknowledged that caffeine in cola-type beverages has been in use well before 1958. However, it was unable to uncover documents that relate to whether caffeine was granted explicit approval and therefore prior sanctioned.

On October 21, 1980, FDA issued a proposed rule setting forth the data collected on caffeine and its preliminary determination that caffeine is not a prior sanctioned ingredient.[5] Based on the scientific evidence that questioned its safety, FDA proposed to delete caffeine from the list of GRAS ingredients. The Agency further provided that the continued use of caffeine would be permitted on an interim basis conditioned on the performance of studies by industry. To resolve the outstanding issue relating to the prior sanction of caffeine, FDA requested individuals to submit evidence that FDA indeed sanctioned the use of caffeine prior to 1958, and failure to respond to the proposed rule constituted a waiver of the right to assert or rely on prior sanction status of caffeine at any time.

The proposed rule not only prompted the review of existing data and information regarding the safety of caffeine, but also fostered new scientific investigations. As a result, valuable, probative data and information supporting the GRAS status of caffeine were assembled and provided to FDA. The proposed rule also resulted in the collection of information that clarified the legal status of the ingredient in soft drinks. In response to the proposed rule, FDA received several comments that presented information supporting the claim that caffeine was prior sanctioned. These events prompted the

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[4] 21 C.F.R. § 182.1180.

[5] 45 Fed. Reg. 69817 (October 21, 1980).

publication of the Caffeine Proposed Rule on May 20, 1987.[6] The Caffeine Proposed Rule revealed that prior to the enactment of the Food Additives Amendment, Coca-Cola Co. received a letter dated August 20, 1958 from John L. Harvey, Deputy Commissioner of FDA at that time, that acknowledged the safety of the components in Coca-Cola and that its ingredients, including caffeine, were sanctioned by the Agency. Both Coca-Cola Co. and NSDA submitted a copy of this letter. In addition, NSDA also submitted other supporting information such as a court-approved settlement involving cola beverage with caffeine, correspondence from FDA regarding the inclusion of caffeine in a standard of identity and the safety of caffeine.

Besides the court-approved settlement, the Agency did not remark on the supporting information provided by NSDA but resolved the issue based solely on the letter from Mr. Harvey. The Agency determined that because of the close proximity in which the letter was issued and the passage of the Food Additives Amendment, that Mr. Harvey understood the significance of the term "sanction." The Agency concluded that the letter from Mr. Harvey was an "explicit approval" and therefore constituted the prior sanction of caffeine. Accordingly, FDA published the Caffeine Proposed Rule to codify the prior sanction of caffeine in nonalcoholic carbonated beverages as required under the regulations.[7] The preamble to the Caffeine proposal sets forth the agency's conclusion that a prior sanction exists for caffeine and the basis for that conclusion.

B. Caffeine Proposed Rule Should Not Be Withdrawn

As demonstrated by its extensive regulatory history, caffeine has been a substance of periodic regulatory attention. Initially, caffeine was determined to be GRAS. After more data became available, the use of caffeine was questioned. Clarification of the regulatory status of caffeine has come only through the rulemaking process, which the Agency is threatening to undo for the mere ministerial purpose of removing the backlog of outdated proposed rules.

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[6] 52 Fed. Reg. 18923 (May 20, 1987).

[7] 21 C.F.R. 181.5(c).

During the GRAS Review, the safety of caffeine was evaluated. Many members of the scientific community, industry and consumer groups participated in this review. Voluminous amounts of data as well as strong and differing opinions were voiced regarding the use of caffeine as a food additive. The rulemaking process revealed critical facts about a previous Agency determination on the use of caffeine in cola-type beverages. Despite the FDA's attempt to research its documents to support the prior sanction of caffeine, the call for documents ultimately produced credible, undisputed evidence that definitely resolved the regulatory status of caffeine as a prior sanction food additive. The Caffeine Proposed Rule established the administrative record and solidified the Agency's conclusion on the prior sanction of caffeine. This proposed rule removes any doubt as to the permissibility of caffeine in nonalcoholic carbonated beverages.

Moreover, the publication of the Caffeine Proposed Rule was the first step in promulgating a final rule. As you know, the regulations require that the Agency promulgate regulations for all known prior sanctioned food additives.[8] NSDA recognizes that the FDA has limited resources. Other more urgent public health issues such as bioterrorism, qualified health claims, and enforcement involving dietary supplements have taken priority over the finalization of this rule. However, the Caffeine Proposed Rule comprises the single document that reflects the Agency's recognition of the special status of caffeine in nonalcoholic carbonated beverages. Furthermore, the Caffeine proposal contains the Agency's conclusion that the use of caffeine in carbonated beverages is consistent with the food safety provisions of the Federal Food, Drug, and Cosmetic Act. This conclusion not only allayed the concerns presented by the 1980 proposal, but also provided an assessment that for years has served as a reference for the Agency's views on the safe use of caffeine. Thus, without question, the conclusion continues to have regulatory and practical utility. Therefore, until such time that the FDA can dedicate the resources necessary to promulgate the final rule for the prior sanction of caffeine, the Caffeine Proposed Rule should not be withdrawn.

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[8] 21 C.F.R. § 181.5(c).

II. COMMENTS TO THE WITHDRAWAL OF THE FOOD LABELING PROPOSED RULE

A. Background – Development of "And/Or" Labeling for Soft Drink Sweeteners

On January 20, 1984, NSDA submitted a Citizen Petition (Docket No. 84P-0029) requesting the FDA to permit the use of "and/or" labeling for sweeteners in soft drinks. NSDA contended that declaration of specific ingredients for soft drink sweeteners was impractical or may result in deception or unfair competition due to fluctuations in the availability of sugar and High Fructose Corn Syrup ("HFCS"). However, the Agency was not convinced by the data initially presented by NSDA. The FDA stated that NSDA did not demonstrate that the same frequency of formulation adjustments occurred with soft drinks as other segments of the food industry where the exemption is permitted (e.g., oils and fats).[9] Therefore, the Agency determined that the "and/or" labeling exemption was not warranted under the circumstances and denied NSDA's Citizen Petition.

Based on a Request for Reconsideration of its Citizen Petition and supplemental data submitted by NSDA, the FDA issued the Food Labeling Proposed Rule on January 6, 1993.[10] In the proposed rule, the Agency acknowledged that NSDA submitted significant data relating to the frequency of reformulation based on availability of sugar and HFCS, cost of maintaining multiple product labels, difficulties in obtaining label supplies from national manufacturers, and special labeling requirements (e.g., kosher for Passover) as well as the additional strains associated with high demand at peak selling periods.

The additional data convinced FDA that the flexibility of an "and/or" labeling system was necessary for declaring sweeteners on soft drink labels, and that the soft drink industry may incur considerable economic consequences without the labeling exemption. The Agency also recognized that this issue was not readily resolved by the granting of a temporary labeling exception, which is the traditional remedy in such situations. Therefore, the FDA determined that the "and/or" labeling exemption is appropriate for

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[9] See 56 Fed. Reg. 28592 (June 21, 1991).

[10] 58 Fed. Reg. 2850 (January 6, 1993).

sweeteners in soft drinks. The soft drink industry has thus made use of and/or labeling with the confidence that neither FDA nor state regulators (who usually follow FDA's lead on matters of this sort) would object.

B. Food Labeling Proposed Rule Should Not Be Withdrawn

The Food Labeling Proposed Rule represents over nine (9) years of NSDA's significant investment in time and resources to compile data, survey member companies, and maintain correspondence with FDA. NSDA furthered the Agency's understanding of the complexities associated with the soft drink labeling, warehousing and distribution and the necessity of the "and/or" labeling exemption for soft drink products. Through its persistence, the soft drink industry was relieved of the onerous and costly task of maintaining numerous types of labels for its products.

The Food Labeling Proposed Rule has clarified the requirements for soft drink product labels and industry has come to rely on the proposed rule as the basis for current Agency policy and industry practice. The proposed rule also provides guidance for the development of future labels for upcoming and seasonal inventories. With over twenty (20) years of use, the "and/or" labeling exemption set forth in the Food Labeling Proposed Rule has proven to be useful to industry and sufficiently clear and not misleading to consumers.

Indeed, the Food Labeling Proposed Rule provides guidance not only to industry but also to FDA. There are instances when the Agency must evaluate the compliance of a food product. The Food Labeling Proposed Rules provides a basis for FDA to exercise its enforcement discretion for soft drink products that may potentially raise misbranding issues and resolve other disputes.

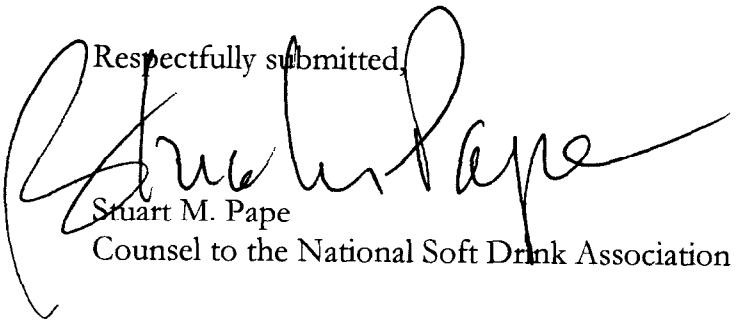
The document institutionalizes the development of the "and/or" labeling exemption and sets forth the Agency's policy on the declaration of sweeteners on soft drink labels. No other document serves this valuable function. To withdraw the Food Labeling Proposed Rule may question current and future labeling practices of the soft drink industry and negate the efforts by NSDA. Therefore, it does not appear that the Agency's administrative goal of removing its backlog exceeds either the potential detrimental consequences that may be suffered by the soft drink industry or the likely regulatory

confusion at the federal and state levels that will arise should FDA withdraw the Food Labeling Proposed Rule.

III. CONCLUSION

Therefore, NSDA respectfully requests that FDA refrain from withdrawing the Caffeine and Food Labeling Proposed Rules. Although the removal of outdated regulations is a laudatory goal, these proposed rules represent the sole source of reference regarding the Agency's position on these matters and to withdraw these rules may potentially call into question scientifically sound and reasonably based industry practices.

Respectfully submitted,



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