THE GLUTAMATE ASSOCIATION
UNITED STATES

July 21, 2003

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

Re: Docket No. 02N-0434; Withdrawal of Certain Proposed Rules and Other Proposed Actions; Notice of Intent; 68 Fed. Reg. 19766 (Apr. 22, 2003)

Dear Sir or Madam:

The Glutamate Association (TGA) appreciates this opportunity to offer comments concerning the above-referenced Food and Drug Administration (FDA) proposal to withdraw outdated proposed rules and other proposed actions. The Glutamate Association (TGA) is a trade association representing manufacturers and users of monosodium glutamate (MSG) and other forms of glutamic acid.

TGA commends the Agency's efforts to eliminate its backlog of pending proposals and agrees that the public interest is served by withdrawing rulemakings that are outdated, stale, problematic, or unnecessary. In particular, TGA supports FDA's intent to withdraw the 1996 advance notice of proposed rulemaking (ANPR) concerning declaration of free glutamate in food, 61 Fed. Reg. 60661 (Sept. 12, 1996).

The 1996 ANPR sought public comment on whether additional labeling requirements were necessary to protect consumers who believe they are sensitive to glutamates in food. The ANPR was prompted, in significant part, by FDA's interpretation of a 1995 report of the Life Sciences Research Office (LSRO) of the Federation of the Federation of American Societies for Experimental Biology (FASEB) concerning the safety of MSG and other glutamate-containing ingredients. FDA interpreted the report to support a conclusion that certain sensitive individuals may experience adverse reactions following the administration of a bolus dose of 3 grams of MSG in a fasting state.

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As TGA commented to the agency at the time of the ANPR's publication, any proposal to require "contains glutamate" labeling would be legally problematic and without a reasonable basis in science. MSG is a widely studied ingredient whose safety repeatedly has been confirmed by every national and international regulatory body that has reviewed the available scientific data. Based on its well established safety record, FDA has historically declined to impose special labeling for MSG or other sources of free glutamate in the past. As TGA explained in 1996, no new data presented in the ANPR warranted a departure from this agency position.

Since the ANPR published, even more data have accumulated to substantiate the safety of MSG. Indeed, a double-blind, placebo-controlled study published in 2000 and conducted at Harvard, Northwestern and the University of California-Los Angeles, evaluated 130 individuals who believed they had a sensitivity to MSG. 1/ The study failed to find any individuals who had consistent, reproducible reactions to MSG. Dr. Saxon, one of the lead researchers in the study, best summarized the results when he said "people have long reported negative reactions to MSG, but if it exists, we could not find it." 2/

In addition to "contains glutamate" labeling, the ANPR sought comment regarding claims such as "no MSG" and "no added MSG." TGA agrees that such claims may be misleading when used on the labels of certain products that contain free glutamate. Although TGA does not object to the establishment of regulatory definitions for these terms, regulatory definitions are not necessary to ensure that food labels are truthful and not misleading. FDA has ample authority under section 403(a) of the FFDCA to take action against the misleading use of "no MSG" and similar claims on any food label or labeling.

1/ Geha R, Beiser A, Ren C, Patterson R, Greenberger P, Grammer L, Ditto A, Harris K, Shaughnessy M, Yarnold P, Corren J. Saxon A, "*Multicenter, double-blind, placebo-controlled, multiple-challenge evaluation of reported reactions to monosodium glutamate,*" J Allergy Clin Immunolog 2000;106:973-80.

2/ *Allergies to MSG May Not Exist,* By Paul D. Thacker, Reuters Health (New York), December 29, 2000.

For the foregoing reasons, TGA fully supports FDA's proposal to withdraw the 1996 ANPR on free glutamate labeling and to focus scarce agency resources on matters likely to yield a public health benefit. For similar reasons, TGA likewise supports the agency's proposal to withdraw the 1993 proposed amendment to the common or usual name regulation for protein hydrolysates, 58 Fed. Reg. 2950 (Jan. 6, 1993), which would have required the term "contains glutamate" as part of the common or usual name of autolyzed yeast extract and certain hydrolyzed proteins. This proposal, like free glutamate labeling, would unnecessarily alarm and mislead consumers about the nature of glutamates.

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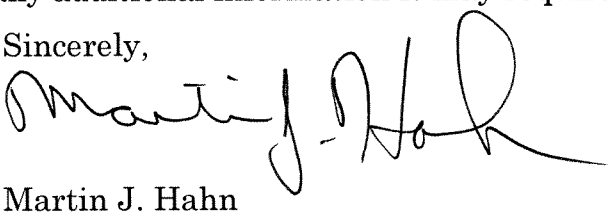
TGA welcomes this opportunity to comment on the ANPR and would be pleased to provide the agency with any additional information it may require.

Sincerely,



Martin J. Hahn
Executive Director
The Glutamate Association