DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Washington DC 20204

August 10, 1994

Ms. Barbara Alexander Mullarkey
Columnist
Wednesday Journal, Inc.
141 S. Oak Park Ave.
Oak Park, IL 60302

Dear Ms. Mullarkey:

This is in response to your July 26 request, for an answer from the Commissioner on the question:

"Of the 112 studies, in the Index of Master File No. 134 for Aspartame, A Nutritive Sweetener with Flavor Enhancing Properties, which are considered pivotal for approval?"

The following studies were considered pivotal.

Entry No. FAMF 134	Title
E-5	An Evaluation of Embryotoxic and Teratogenic Potential in the Rat (SC-18862)
E-11	Two Generation Reproduction Study in Rats (SC-18862)
E-28	106-Week Oral Toxicity Dog Study (SC-18862)
E-32	52-Week Oral Toxicity in the Infant Monkey (SC-18862)
E-33	Appendix: Two-Year Toxicity Study in the Rat (SC-18862)
E-34	Two-Year Toxicity study in the Rat (SC-18862)
E-70	Lifetime Toxicity Study in the Rat (SC-18862)
E-75	104-Week Toxicity in the Mouse (SC-18862)
E-76	110-Week Toxicity Study in the Mouse (SC-19192)

E-77 & 78	115-Week Oral Tumorigenicity Study in the Rat (SC-19192)
E-86	A Supplemental Study of Dog Brains from a 106-Week Oral Toxicity Study (SC-18862)
E-87	A Supplemental Study of Rat Brains from Two Tumorigenicity Studies (SC-18862)
E-89	An Evaluation of Embryotoxic and Teratogenic Potential in the Mouse (SC-18862)
E-90	An Evaluation of Embryotoxic and Teratogenic Potential in the Rabbit (SC-18862)

We also note there were others studies of interest in considering the safety review for aspartame approval.

Sincerely yours,

Rudolph Harris

Rudolph Harris, Ph.D.
Branch Chief
Novel Ingredients Branch, HFS-207
Center for Food Safety
and Applied Nutrition

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MAR 23 1989

Ms. Barbara A. Mullarkey
Columnist
Wednesday Journal of Oak Park
& River Forest
141 S. Oak Park Avenue
Oak Park, IL 60302

Dear Ms. Mullarkey:

This responds to your letter of March 8, 1989, concerning the list of over a hundred articles included in the master file No. 134 on aspartame. You asked which studies have been peer reviewed by scientific journals and which were Searle-funded.

Since all these studies were submitted by the NutraSweet Company, we believe that the majority, if not all, of them were Searle-funded. We have no requirements as to knowing who their financial sponsors are. Therefore, you are advised to obtain this type of information directly from the NutraSweet Company.

Moreover, the majority of these studies were not published in scientific journals at the time we received them. However, a portion of them were published later. We have no requirement that the petitioner inform us where or when he publishes the data that have been submitted to support the safety of aspartame. Therefore, we are unable to inform you which studies have been published in scientific journals (thereby having been peer reviewed by scientists outside the FDA). However, we wish to emphasize that for those that are not published, our careful in-house review of the primary data by a number of qualified scientists constitutes peer review.

Sincerely yours,

Lawrence J. Lin

Lawrence J. Lin, Ph.D.
Direct Additives Branch, HFF-334
Division of Food and Color Additives
Center for Food Safety
and Applied Nutrition

NUTRIVOICE
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11 July 1995

To: U.S. Representatives & U.S. Senators
From: Barbara Alexander Mullarkey

Will you demand that FDA officials protect our food supply by mandating a moratorium on aspartame/NutraSweet/Equal until independent, corporate-neutral researchers verify its safety.

On April 20, 1995, the FDA reported 10,386 volunteered aspartame complaints of 92 symptoms. FDA Commissioner David Kessler reported in the June 2, 1993, JAMA, that, "only about 1% of serious events are reported to the FDA." If aspartame were a drug instead of a food additive, the FDA would have removed it from the marketplace. Since 1988, thirteen aviation magazines have warned pilots of aspartame's side effects. The FAA refuses to warn pilots of aspartame's side effects because the FDA continues to support its safety.

On June 12, 1995, Food Chemical News stated: "FDA has no further plans to continue to collect adverse reaction reports or monitor research periodically done on aspartame, Wilcox said."

Thomas Wilcox is FDA epidemiology branch chief. The same article stated, "Wilcox told Community Nutrition Institute's May 26 Nutrition Week publication that aspartame complaints represent 75% of all reports of adverse reactions to substances in the food supply received by the FDA since 1981. He told CNI that although aspartame has been approved for 14 years, 'there is still concern' about the substance and that 'some people have an intolerance (to aspartame), as is true of other chemicals in the food supply."

What will you do?