

HARTMAN & CRAVEN LLP

460 PARK AVENUE

NEW YORK, N.Y. 10022-1987

TEL: (212) 753-7500

FAX: (212) 688-2870

NEAL T. DORMAN  
JOEL I. FRANK  
ROBERT L. FROMER  
SHARON H. JACOBY  
STEVEN A. KIRSCHENBAUM  
GARY KISSIN  
RICHARD H. KOBY  
MARK R. KOOK  
VICTOR M. METSCH  
STEPHEN W. O'CONNELL<sup>†</sup>  
EDWARD L. SCHIFF  
EDWARD I. TISHELMAN  
ELIOT H. ZUCKERMAN

JUN 12 2002 10:12 AM  
STUART Z. KRINSKY  
COUNSEL

BRIAN J. BUTTIGIEG  
PATRICK M. CALELLA<sup>†</sup>  
STEWART LOUIE  
GEORGE MILLER, JR.<sup>†</sup>  
KIMBERLY M. SEIB  
GLENN H. SPIEGEL

<sup>†</sup>ALSO ADMITTED IN NEW JERSEY

WRITER'S DIRECT DIAL

June 11, 2002

VIA FEDERAL EXPRESS

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

Re: Docket No. 99F-0187; FAP 9A4643; Neotame

On August 16, 2000, on behalf of our client, the undersigned submitted comments to the above-referenced docket. Those comments identified a number of concerns that pertain to the adequacy of the safety data submitted in support of FDA's approval of neotame. In particular, the comments questioned the adequacy of the data in resolving issues regarding the body weight gain of test animals consuming neotame, and their reported food consumption values.

Our client has monitored developments on this petition through periodic reviews of the docket and Freedom of Information Act requests. These reviews have not uncovered any material submitted by the petitioner that addresses the body-weight gain issue. Our client continues to believe that there is insufficient data concerning the toxic effect on growth to resolve this issue. The body weight gain issue impacts the establishment of a no effect or no adverse effect level and must, therefore, be evaluated closely. Our client believes these issues can be resolved only through the generation of additional data, as outlined in our earlier comments.

99F-0187

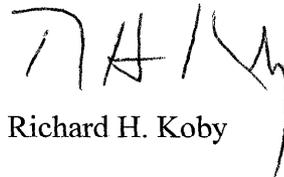
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Serious concerns raised by our client require definitive resolution to remove any remaining doubts about the safety of neotame prior to its introduction into the marketplace, and, equally important, to assure reasonable certainty that no harm will result from consumption of neotame. The Agency and public should have the opportunity to review the additional data needed to address these issues, along with appropriate explanations prior to the issuance of a final rule.

Thank you for your attention to this matter.

Very truly yours,

A handwritten signature in black ink, appearing to read 'RHK', with a stylized flourish extending from the end.

Richard H. Koby

Cc: Dr. Blondell Anderson  
Dr. Alan Rulis

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