

RICHARD R. REO ASSOCIATE DIRECTOR REGULATORY AFFAIRS

September 5, 2000

Via Fax 202-205-0165
Mr. Charles W. Copper
Office of Constituent Operations
HFS-585
CFSAN
Food and Drug Administration
200 C Street SW
Washington, DC 20204

00-041N 00-041N-6 Richard R. Reo

Re: Addition of Sucralose to the Proposed Draft Standard for Chocolate and Chocolate Products

Dear Mr. Cooper:

McNeil Specialty Products Company requests that the nonnutritive sweetener, sucralose, be added as a permitted sweetener to the Codex Committee on Cocoa Products and Chocolate Proposed Draft Standard for Chocolate and Chocolate Products.

McNeil supports the Codex efforts to permit flexibility in the products covered by the chocolate standard. The use in chocolate products of safe and suitable sweeteners, such as sucralose, will stimulate innovation by confectionery producers and benefit consumers by permitting good tasting lower calorie alternatives to full calorie chocolate products.

Sucralose is currently permitted for broad use, including confectionery products, in over thirty countries. In the U.S., FDA permits the use of sucralose as a "general purpose sweetener" with a use level governed by Good Manufacturing Practice (GMP). The U.S. FDA food additive petition for sucralose (FAP 7A3987) contained specific product application data demonstrating the usefulness of sucralose as a sweetener in confectionery products, including cocoa and chocolate-based confections. In Canada and Australia, sucralose is permitted for use in chocolate-based confectionery products at use levels of 700 mg/kg and 1,500 mg/kg, respectively. Moreover, in June 1990, JECFA allocated to sucralose (INS #955) an acceptable daily intake of 0-15 mg/kg bodyweight/day.

Mr. Charles W. Cooper September 5, 2000 Page 2

Based on the current approvals, we request that the Codex standard on Chocolate and Chocolate Products include sucralose as a permitted sweetener and specify an upper use level of 1000 mg/kg for the finished product, as consumed.

McNeil supports the Codex efforts to allow more flexibility in the standards for chocolate products and appreciates the opportunity to comment.

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Sincerely,

Richard R. Reo