

U.S. Food and Drug Administration

## *FDA Talk Paper*

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### **FDA APPROVES NEW NON-NUTRITIVE SUGAR SUBSTITUTE NEOTAME**

The Food and Drug Administration today announced its approval of a new sweetener, neotame, for use as a general-purpose sweetener in a wide variety of food products, other than meat and poultry. Neotame is a non-nutritive, high intensity sweetener that is manufactured by the NutraSweet Company of Mount Prospect, Illinois.

Depending on its food application, neotame is approximately 7,000 to 13,000 times sweeter than sugar. It is a free-flowing, water soluble, white crystalline powder that is heat stable and can be used as a tabletop sweetener as well as in cooking applications. Examples of uses for which neotame has been approved include baked goods, non-alcoholic beverages (including soft drinks), chewing gum, confections and frostings, frozen desserts, gelatins and puddings, jams and jellies, processed fruits and fruit juices, toppings and syrups.

In determining the safety of neotame, FDA reviewed data from more than 113 animal and human studies. The safety studies were designed to identify possible toxic effects, such as cancer-causing, reproductive, and neurological effects. From its evaluation of the neotame database, the FDA was able to conclude that neotame is safe for human consumption.

New food additives, including new sweeteners, must be approved by FDA as safe before they may be marketed in the United States.

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**§ 172.829 Neotame.**

(a) Neotame is the chemical *N*-[*N*-(3,3-dimethylbutyl)-*L*- $\alpha$ -aspartyl]-*L*-phenylalanine-1-methyl ester (CAS Reg. No. 165450-17-9).

(b) Neotame meets the following specifications when it is tested according to the methods described or referenced in the document entitled "Specifications and Analytical Methods for Neotame" dated April 3, 2001, by the NutraSweet Co., 699 North Wheeling Rd., Mount Prospect, IL 60056. The Director of the Office of the Federal Register has approved the incorporation by reference of this material in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740. Copies may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., rm. 1C-100, College Park, MD 20740, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC 20001.

(1) Assay for neotame, not less than 97.0 percent and not more than 102.0 percent on a dry basis.

(2) Free dipeptide acid (*N*-[*N*-(3,3-dimethylbutyl)-*L*- $\alpha$ -aspartyl]-*L*-phenylalanine), not more than 1.5 percent.

(3) Other related substances, not more than 2.0 percent.

(4) Lead, not more than 2.0 milligrams per kilogram.

(5) Water, not more than 5.0 percent.

(6) Residue on ignition, not more than 0.2 percent

(7) Specific rotation, determined at 20 °C [ $\alpha$ ]<sub>D</sub>: -40.0° to 43.4° calculated on a dry basis.

(c) The food additive neotame may be safely used as a sweetening agent and flavor enhancer in foods generally, except in meat and poultry, in accordance with current good manufacturing practice, in an amount not to exceed that reasonably required to accomplish the intended technical effect, in foods for which standards of identity established under section 401 of the Federal Food, Drug, and Cosmetic Act do not preclude such use.

(d) When neotame is used as a sugar substitute tablet, L-leucine may be used as a lubricant in the manufacture of tablets at a level not to exceed 3.5 percent of the weight of the tablet.