

ASPARTAME SIDEBARS

ASPARTAME'S HISTORY OF POLITICAL INTRIGUE

Aspartame was discovered in 1965 by a scientist working for pharmaceutical behemoth G.D. Searle and Company. Recognizing a potential cash, G.D. Searle and Co set about gaining FDA approval for their entry into the lucrative artificial sweetener market. In a 1970 internal memo, company officials laid out a strategy of “bringing the FDA into a subconscious spirit of participation.” Our approach ...should be to try to get them to say “Yes,” to rank the things that we are going to ask for, so we are putting first those questions we would like to get a “yes” to, even if we have to throw some in that have no significance, other than putting them in a yes saying habit.

The first scientists who conducted clinical studies on aspartame, biochemist Dr. Harry Waisman and neuroscientist Dr. John W. Olney, gave it thumbs down. Searle's only reaction to their findings was to use their own scientists — or those of their favorite contractor — throughout the rest of approval process. Waisman's results, when reported to the FDA, were falsified, while Olney's were hidden from sight, techniques the company would continue to use in all their dealings with the FDA and other government and consumer agencies concerning aspartame.

Searle's slight of hand was noted early on by a number of FDA scientists and officials, but in July of 1974, the director of the FDA approved aspartame for limited use. Before it could go on the market, however, Dr. Olney and James Turner Esq. filed a formal objection, stating they believed that aspartame had the potential to cause brain damage, and that they were particularly concerned about its effects on children. Searle's non-response to the subsequent questions about their methodology set off a controversy within the FDA, and a special in-house Task Force was convened to examine the key studies done on aspartame and a number of pharmaceuticals.

The task force's preliminary findings caused the FDA to put a hold on aspartame's approval. Further obfuscation by Searle led FDA Chief Counsel Richard Merrill to recommend a grand jury be convened to investigate Searle — a recommendation that ran into a brick wall when presiding U.S. Attorney Sam Skinner left his job to work for Sidley & Austin, G.D. Searle's law firm. Following Skinner's departure, Assistant U.S. Attorney William Conlon convened a grand jury, but let the statute of limitations run out on the complaint. Fifteen months later he, too, went to work for Sidley & Austin.

In 1977, amidst continued rumblings about the company's fraudulent research, Searle brought out the Big Gun. **Donald Rumsfeld**, former Chief of Staff in the Ford administration — and current Secretary of Defense — was hired as president of the company. Though it took nearly four years, Rumsfeld eventually proved to be worth his weight in artificial sweetener. The day after Ronald Reagan took office in 1980, G.D. Searle reapplied for FDA approval of aspartame. At that time, according to a former Searle employee, Rumsfeld told his sales force that, “he would call in all his markers and that no matter what, he would see to it that aspartame would be approved that year.” Six months later, it was approved (for use in dry foods only) by the new, Reagan-appointed Commissioner of the FDA.

Soon after, an amendment was attached to the Orphan Drug Act which extended Searle's patent on aspartame by 5 years, 10 months and 17 days. The bill passed, speeded along by **Utah Senator Orrin Hatch**, who later received \$2,500 from the soft drink political action committee, and \$1,000 each from William and Daniel Searle and a Searle brother-in-law and William Searle. Since then, Hatch has been an outspoken advocate for the sweetener, possibly due to his holdings in **Twin Lab**, a health supplement company that uses aspartame in a number of their products. Between 1979 and 1982, four FDA officials

who assisted in the aspartame approval process landed jobs in artificial sweetener industry. In 1983, aspartame was approved for use in carbonated beverages. Shortly after, the Commissioner of the FDA, Arthur Hayes, left the FDA under charges of impropriety, and was hired as a consultant with Searle's public relations firm, Burson Marsteller [at \$1,000 a day]. That same year, James Turner, Esq. filed a petition with the FDA on behalf of himself and Community Nutrition Institute objecting to the approval of aspartame. Three months later, the FDA denied the request "because public interest did not require it."

In May of 1985, the U.S. Senate heard testimony relating to an amendment put forth by **Senator Howard Metzenbaum** requiring the quantity of aspartame used in products to be labeled. Senator Orrin Hatch led the fight against the labeling amendment, which was defeated. Three months later, Metzenbaum introduced the Aspartame Safety Act of 1985, another attempt at labeling, that also mandated a moratorium on new uses of aspartame until independent research could be conducted by the National Institutes of Health. The bill died in the Senate.

Also in 1985, G.D. Searle sold the NutraSweet Company (the subsidiary formed by Searle to market aspartame) to the Monsanto Company, over the objections of Monsanto's stockholders, who were leery of the legal liabilities associated with the product.

In November, 1987, a hearing was held in a U.S. Senate Committee to address aspartame safety and proposed labeling. Senator Orrin Hatch once again blocked the proceedings.

The patent for aspartame expired in December of 1992, opening up the market to other companies, such as the Holland Sweetener Company.

In 1996, the FDA approved aspartame for "general use," allowing it to be used in baking and cooking.

In 1999, Brand Week magazine named NutraSweet one of the top 100 brands of the century. NutraSweet brand aspartame is sold in more than 100 countries and used in approximately 5,000 products by 250 million people on a regular basis.

In May 2000 The J.W. Childs company purchased the NutraSweet Company from Monsanto for \$440 million in cash. The sale includes the sweetener business, the NutraSweet brand name and rights to the company's new sweetener, neotame.

"The NutraSweet Company revolutionized the sweetener industry in 1981 with the introduction of aspartame," says Nick Rosa, the new president and CEO of the NutraSweet Company, "and we intend to do it again with neotame when we receive approval from various regulatory agencies around the world." •

OTHER NON-CALORIC SWEETENERS

In the United States, the Food and Drug Administration (FDA) permits six low-calorie sweeteners to be used as food additives: Saccharin, aspartame (known around the world as NutraSweet, Equal, Spoonfuls, Canderel, Bienvia, NatraSweet and Miwon), acesulfame K, (sold under the brand name Sunett), sucralose (marketed as Splenda), trehalose and tagatose.

Saccharin

Discovered in 1879, saccharin was initially used as an antiseptic and a food preservative. Its use as a sweetener developed slowly until World Wars I and II, when sugar rationing caused its popularity to boom. The FDA has allowed the makers of saccharin to make a self-determined Generally Recognized As Safe (GRAS) declaration, claiming exemption from the premarket or food additive approval requirements, although the FDA also lists it as an "anticipated" human carcinogen. All saccharin-sweetened products must bear a label stating: "Use of this product may be hazardous to your health. This product contains saccharin which has been determined to cause cancer in laboratory animals."

Acesulfame-K (Sunette)

Acesulfame-K (5,6-dimethyl-1,2,3-oxathiazine-4(3H)-one-2,2-dioxide) is approximately 200 times sweeter than sucrose. It has been approved by the FDA in 1988 for use in baked goods, refrigerated and frozen desserts, alcoholic beverages, yogurt, dry dessert mixes, confections, hard and soft candies, tabletop sweeteners, bulk sweeteners, chewing gum, dry dairy analog bases, syrups, sweet sauces and toppings. Acesulfame K, produced by Hoechst Food Ingredients in Germany, is often used in combination with other artificial sweeteners, such as aspartame and saccharin. The Center for Science in the Public Interest, a food watchdog agency, has repeatedly expressed concern that acesulfame K is a potential carcinogen, and that the FDA has failed to require the manufacturer to conduct high-quality tests of the artificial sweetener.

According to CSPI, testing done on acesulfame K "followed inadequate protocols, which are greatly at variance with current standards for test design, execution and reporting required for the National Toxicology Program's bioassays."

Sucralose (Splenda)

Sucralose (trichlorogalactosucrose) was approved by the FDA in 1988 as a tabletop sweetener and for use in a number of desserts, confections, and nonalcoholic beverages. Sucralose is produced by chlorinating sucrose (sugar); three chlorine atoms are substituted for three hydroxyl groups. According to Consumers Research Magazine, some concern was initially raised about sucralose being a chlorinated molecule, as chlorinated molecules also serve as the basis for pesticides such as D.D.T., and accumulate in body fat. However, the manufacturer, Johnson & Johnson emphasized that "sucralose passes through the body unabsorbed."

Research animals fed sucralose exhibited the following symptoms: Shrunken thymus glands (up to 40% shrinkage), enlarged liver and kidneys, atrophy of lymph follicles in the spleen and thymus, reduced growth rate, decreased red blood cell count, hyperplasia of the pelvis, extension of the pregnancy period, aborted pregnancy, decreased fetal body weights and placental weights and chronic diarrhea.

In the wake of the continued controversy over aspartame, many pharmaceutical and health food manufacturers — including Pro Lab, Twin Lab and Ross Products, makers of Pedialyte) — have switched over to sucralose.

Tagatose & Trehalose

Like saccharin, both of these sweeteners have slipped through the FDA with a Generally Recognized As Safe (GRAS) status.

The Calorie Control Council — which enthusiastically endorses the use of all artificial sweeteners — describes tagatose as "a naturally occurring reduced-calorie sweetener that can be found in some dairy products" and "commercially produced via a patented process." Less sweet than sugar, tagatose also "browns" more readily than sucrose in baked goods, and has been shown to cause diarrhea and gas. Nonetheless, manufacturers plan to use tagatose in chocolate, caramel, chewing gum, ice cream, soft drinks, cereals and meal replacements.

Trehalose is almost half as sweet as table sugar, and is said to occur naturally in honey, mushrooms, lobster, shrimp and foods produced using baker's and brewer's yeast. It is approved for use in beverages,

including fruit juices, purees, fillings, nutrition bars, dehydrated fruits and vegetables and white chocolate for cookies or chips. though because of its low sweetness rating, trehalose is most often used as a preservative.

And On the Horizon...

Alitame,

Discovered by Pfizer, Inc., alitame (brand name Aclame) is 2,000 times sweeter than sugar. Like aspartame, it is made from amino acids, including aspartic acid, D-alanine and a novel amine. Alitame has the potential to be used in almost all areas where sweeteners are presently used —e.g., baked goods and baking mixes, hot and cold beverages, dry beverage mixes, milk products, frozen desserts and mixes, fruit preparations, chewing gums and candies, tabletop sweeteners, toiletries and pharmaceuticals.

Pfizer applied for FDA approval of alitame in 1986, but it has yet to be granted. It is, however, available in other countries, including Australia, New Zealand and the People's Republic of China.

Neotame

Neotame contains all the dangerous elements of aspartame and more: the amino acids L-aspartic acid and L-phenylalanine, and two organic functional groups: one known as a methyl ester group and the other as a neohexyl group. These components are joined together to form an incredibly sweet (8,000 times sweeter than sugar) and potentially dangerous compound.

The FDA was petitioned in 1997 to approve neotame for use as a tabletop sweetener. Approval is still pending. The NutraSweet Company, which owns the right to neotame, plans to use the sweetener in chewing gum, carbonated soft drinks, refrigerated and non-refrigerated ready-to-drink beverages, frozen desserts and novelties, puddings and fillings, yogurt-type products, baked goods and candies.

Cyclamate

Cyclamate was first introduced as a sweetener in the early 1950s, and dominated the artificial sweetener market through much of the '60s. In the late 60s, however, concerns arose over cyclamate's potential to cause genetic damage, testicular atrophy and cancer, and in 1970, the FDA imposed a total ban on its use. Under pressure from the sweetener industry, the FDA is said to be considering reapproval of cyclamate, which is still in use in 50 other countries. In many products made overseas and shipped to the United States, cyclamate, Acesulfame-K and aspartame are blended together to create a "super sweetener." •