



CFSAN/Office of Food Additive Safety  
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## FDA Statement on European Aspartame Study

FDA has completed its review concerning the long-term carcinogenicity study of aspartame entitled, "Long-Term Carcinogenicity Bioassays to Evaluate the Potential Biological Effects, in Particular Carcinogenic, of Aspartame Administered in Feed to Sprague-Dawley Rats," conducted by the European Ramazzini Foundation (ERF), located in Bologna, Italy. FDA reviewed the study data made available to them by ERF and finds that it does not support ERF's conclusion that aspartame is a carcinogen. Additionally, these data do not provide evidence to alter FDA's conclusion that the use of aspartame is safe.

Aspartame was first approved in the United States in 1981 and is one of the most widely used artificial sweeteners. When metabolized by the body, aspartame is broken down into two common amino acids, aspartic acid and phenylalanine, and a third substance, methanol. These three substances are available in similar or greater amounts from eating common foods.

Upon first learning of the ERF study results, FDA requested the data from ERF to evaluate the findings. On February 28, 2006, the agency received only a portion of the study data requested. In June 2006, FDA asked ERF to provide the remainder of the study data initially requested and also offered to review pathology slides from the study. ERF did not submit additional data to FDA and did not agree to FDA's review of the pathology slides.

FDA could not conduct a complete and definitive review of the study because ERF did not provide the full study data. Based on the available data, however, we have identified significant shortcomings in the design, conduct, reporting, and interpretation of this study. FDA finds that the reliability and interpretation of the study outcome is compromised by these shortcomings and uncontrolled variables, such as the presence of infection in the test animals.

Additionally, the data that were provided to FDA do not appear to support the aspartame-related findings reported by ERF. Based on our review, pathological changes were incidental and appeared spontaneously in the study animals, and none of the histopathological changes reported appear to be related to treatment with aspartame. FDA believes that additional insight on the study findings could be provided by an internationally-sponsored pathology working group examination of appropriate tissue slides from the study.

Considering results from the large number of studies on aspartame's safety, including five previously conducted negative chronic carcinogenicity studies, a recently reported large epidemiology study with negative associations between the use of aspartame and the occurrence of tumors, and negative findings from a series of three transgenic mouse assays, FDA finds no reason to alter its previous conclusion that aspartame is safe as a general purpose sweetener in food.