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FDA reviews Italian aspartame study

By Lorraine Heller

4/23/2007- **The US Food and Drug Administration (FDA) has reaffirmed its position on the safety of aspartame, following a review of a European study that had linked the artificial sweetener to cancer.**

The regulatory agency on Friday said it does not support the conclusion of the Italy-based European Ramazzini Foundation (ERF) study that aspartame is a carcinogen.

The announcement comes after an FDA review of ERF data. However, the agency said it could not conduct a complete and definitive review of the study because ERF did not provide the full study data.

The data it was able to review did not support the ERF conclusions, said FDA.

The Ramazzini findings, published in 2005, followed a long-term feeding study on aspartame conducted on rats.

On learning of the study results, FDA requested the study data from Ramazzini so as to evaluate the findings. On February 28, 2006, the agency received a portion of the data requested. In June 2006, FDA asked ERF to provide the remainder of the study data and also offered to review pathology slides from the study.

FDA said ERF did not submit additional data to the agency and did not agree to FDA's review of the pathology slides.

"Based on the available data (…) 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," it said.

"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 suggested 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.

A review of the study by the European Food Safety Authority (EFSA) also found the conclusions flawed. Iona Pratt, chair of a group of scientists who reviewed the Ramazzini study for EFSA, said that it did not reveal any evidence that would point to aspartame as a cancer causing agent.

Aspartame is currently used in a variety of food and beverage items, such as yogurt, desserts and carbonated drinks. FDA approved aspartame for consumption in 1981.

Current estimation sets the nation's total aspartame consumption at 8,040 tons per year, with the acceptable daily intake set by the FDA being 50mg aspartame/kg body weight.

Since its discovery in 1965 aspartame has be the source of controversy within the scientific community and industry over whether it causes health problems. Some studies have indicated a health risk, some have indicated that it does not cause harm to humans. Industry has consistently denied that the artificial sweetener poses a health risk, claiming that the numerous scientific studies were faulty.

They also point to four previous long term studies sponsored by G.D. Searle, a chemical company

that held the patent to aspartame, which were the basis for regulatory acceptance worldwide. Searle was later bought by Monsanto and became NutraSweet Co.

"The overwhelming body of scientific evidence clearly demonstrates that aspartame, even in amounts many times what people typically consume, is safe and not associated with adverse health effects," claims the Aspartame Information Center, an industry funded body.

However Kathryn Knowles, a spokesperson for Ramazzini, said that the Ramazzini research was the first long term independent study relating to cancer.
Knowles said the study should be a valuable lesson for industry, which can learn from the experience, no matter if it turns out to be painful.

"There should be a quality assurance partnership between researchers and the food additive industry," she said. *"There should be independent evaluations using long term studies."*