



For Immediate Release

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Overwhelming Scientific Evidence Confirms Safety of Aspartame

Governments Recommend No Change in Dietary Practices Related to Aspartame

ATLANTA (November 17, 2005) – The Calorie Control Council today stated that a rat study conducted by Italy’s Ramazzini Institute is totally contradictory with the extensive scientific research and regulatory reviews conducted on aspartame. The U.S. Food & Drug Administration (FDA) has said they are not recommending any changes in the use of aspartame. The study, to be published in *Environmental Health Perspectives*, a publication of the National Institute of Environmental and Health Sciences (NIEHS), alleges that aspartame may be related to an increased risk of leukemia and lymphoma in rats. The design and execution of the study did not follow guidelines set up by the National Toxicology Program (NTP), the U.S. government toxicology initiative administered by the NIEHS.

In October 2005, NIEHS informed the Calorie Control Council, “The NTP has convened a group of pathologists to review selected histopathological lesions from the RF [Ramazzini Foundation] aspartame cancer bioassays. The NIEHS has not carried out a systematic pathology review of the RF aspartame studies.” NIEHS has confirmed that it had no role in the design, performance or interpretation of the Ramazzini study and stated it is not putting NIEHS’ reputation behind this study.

Ramazzini researchers did not follow internationally established protocols for evaluation of animal carcinogenicity study findings. Further, the NTP and other organizations have established guidelines for pathology peer review in order to provide scientific consensus that study

conclusions are valid. Such an independent review of the pathology slides from this study has not been conducted.

NTP has recently completed three animal studies designed to evaluate whether aspartame is capable of causing cancer. These U.S. government funded and managed studies were conducted using Good Laboratory Practice (GLP) and the results were peer-reviewed by individuals considered experts in their profession. The results of these cancer studies, in which aspartame was fed at levels similar to those reportedly fed in the Ramazzini study, unequivocally indicated that “there was no evidence of carcinogenic activity [cancer] of aspartame.”

Previous findings by the Ramazzini researchers at the same institution using a similar protocol have been reviewed by the FDA’s Cancer Assessment Committee, which noted that those reported data were “unreliable” due to a “lack of critical details ... and ... questionable histopathological conclusions... .” The aspartame findings from the Ramazzini researchers recently were reviewed by the expert United Kingdom Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment. Members of that Committee characterized aspects of study findings as “implausible,” with other aspects “cast(ing) doubt” on the entire study. Members of the committee were “critical” of the study design and the statistical approach used.

Four long-term carcinogenicity studies on aspartame conducted in accordance with international standards have found no relationship between aspartame and any form of cancer. The studies were submitted to numerous regulatory agencies, such as the FDA, which conducted exhaustive reviews of the data. When FDA approved aspartame, the FDA Commissioner noted: “Few compounds have withstood such detailed testing and repeated, close scrutiny, and the process through which aspartame has gone should provide the public with additional confidence of its safety.”

Based on the current information from Ramazzini, the European Food Safety Authority (EFSA) (a scientific body charged with providing independent and objective advice on food safety issues in the European Union) stated, “EFSA does not consider it appropriate to suggest any change in consumers’ diets relative to aspartame... .”

All of the approved low-calorie sweeteners, including aspartame, have been determined to be safe by the FDA and other scientific and regulatory authorities worldwide. Aspartame has been safely consumed for nearly a quarter of a century and is one of the most thoroughly studied food ingredients, with more than 200 scientific studies confirming its safety. In addition to the FDA, the Joint Expert Committee on Food Additives (JECFA) of the World Health Organization and Food and Agriculture Organization, the Scientific Committee on Food of the European Union and regulatory agencies in 130 countries have reviewed aspartame and found it to be safe for use.

Aspartame is composed of two amino acids, aspartic acid and phenylalanine, as the methyl ester. Amino acids are the building blocks of protein. Aspartic acid and phenylalanine are found naturally in protein containing foods, including meats, grains and dairy products. Methyl esters are also found naturally in many foods such as fruits and vegetable and their juices. The body handles the components from aspartame in the same way it handles them when derived from other foods.

“Consumers and health professionals can be assured that aspartame is safe for humans. And the rigorous scrutiny and battery of studies to which aspartame has been subjected should provide people with additional confidence in its safety,” stated Lyn Nabors, President of the Calorie Control Council.

For more information please visit www.aspartame.org.

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The Calorie Control Council, established in 1966, is an international non-profit association representing the low-calorie and reduced-fat food and beverage industry.