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Date: Thu, Jul 13, 2023 at 9:33 PM
Subject: ICYMI: FDA Statement on the Safety of Aspartame

Sharing the FDA statement that reiterates the safety aspartame.

Attributable to the FDA, an FDA official or an FDA spokesperson:

The FDA is aware of the International Agency for Research on Cancer (IARC) and Joint FAO/WHO Expert Committee on Food Additives (JECFA) conclusions about aspartame issued July 14, 2023. Aspartame being labeled by IARC as "possibly carcinogenic to humans" does not mean that aspartame is actually linked to cancer.

The FDA disagrees with IARC's conclusion that these studies support classifying aspartame as a possible carcinogen to humans. FDA scientists reviewed the scientific information included in IARC's review in 2021 when it was first made available and identified significant shortcomings in the studies on which IARC relied. We note that JECFA did not raise safety concerns for aspartame under the current levels of use and did not change the Acceptable Daily Intake (ADI).

Aspartame is one of the most studied food additives in the human food supply. FDA scientists do not have safety concerns when aspartame is used under the approved conditions. The sweetener is approved in many countries. Regulatory and scientific authorities, such as Health Canada and the European Food Safety Authority have evaluated aspartame and also consider it safe at current permitted use levels.

Some consumers may rely on products with aspartame and other sweeteners to help reduce their sugar consumption. We recognize that navigating different information from health organizations is challenging. We will continue to provide reliable, science-based information on aspartame and other sweeteners on the FDA's web site to help consumers make informed choices.

On Background:

The FDA evaluated the same studies that IARC relied on to support their findings. We identified significant shortcomings in the design, conduct, reporting, and interpretation of the animal study used to support the IARC's conclusion. The FDA found that the reliability and interpretation of the study outcome was compromised by these shortcomings and uncontrolled variables, such as the presence of infection in the test animals. The FDA has reviewed other studies that do not show evidence of carcinogenicity for aspartame. Therefore, the FDA does not agree with IARC's conclusion.

On behalf of the Unites States, the Department of Health and Human Services sent a letter to the World Health Organization (WHO) outlining our concerns with IARC and JEFCA, both part of the WHO, conducting reviews of aspartame. In that letter, we recommended that JEFCA was

better suited to conduct the review because of their expertise in reviewing food additives, among other reasons. It is important to note that IARC did a hazard assessment, which is different from JECFA's risk assessment of aspartame's current levels of use. For example, IARC does not factor dosage or route of exposure into its classifications, and those are critical variables to assess health risk.

During pre-market review, the FDA established an Acceptable Daily Intake (ADI) level for each of the six sweeteners approved as food additives. For example, for aspartame, a person who is 132 pounds would need to consume 75 packets of this sweetener per day to reach the FDA's ADI and that is assuming that a packet of aspartame is as sweet as two teaspoons (approximately 8 grams) of sugar. An additive does not pose safety concerns if the estimated daily intake is less than the ADI. This chart shows the safe limit for each sweetener and the amount a person would need to consume to equal that limit based on its sweetness intensity. An ADI is the amount of a substance considered safe to consume each day over the course of a person's lifetime. For each of these sweeteners, the FDA determined that the estimated daily intake of the substance would not exceed the ADI, even when considering high exposure estimates.

For more information, see:

1. Aspartame and Other Sweeteners in Food | FDA
2. Consumer Update: How Sweet It Is: All About Sugar Substitutes
3. Timeline of Selected FDA Activities and Significant Events Addressing Aspartame
4. EFSA: Scientific Data on Aspartame