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FDA RELEASES FINAL RULE ALLOWING VOLUNTARY RISK REVIEWS OF FOOD ADDITIVES TO CONTINUE

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The Food and Drug Administration (FDA) says its final rule allowing outside groups to evaluate food additive risks will streamline its "Generally Recognized as Safe" (GRAS) reviews.

The agency recently released its GRAS final rule for its food additive program, switching reviews from a more formal but slower "petition-based" process to a voluntary "notification" process.

Under the federal Food, Drug and Cosmetic Act (FD&C Act), any substance that is intentionally added to food is a food additive that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excepted from the definition of a food additive.

The use of a food substance may be GRAS either through scientific procedures or, for a substance used in food before 1958, through experience based on common use in food, which requires a substantial history of consumption for food use by a significant number of consumers.

Rule adopts pilot voluntary notification program.

The FDA's rule implements as final a pilot notification program under which food makers can convene their own expert panels to prepare GRAS reviews and provide notice to the FDA.

Under the former petition-based process the agency would publish an order in the Federal Register listing the substance as GRAS, and issue a corresponding regulation that prescribes the safe conditions of its use. If it determined the substance was not GRAS, then the agency would notice that in the Federal Register.

According to the FDA's review of its notification pilot program, "experience also has shown that streamlining our evaluation of conclusions of GRAS status will enable us to evaluate more, and higher priority, substances." Since the pilot program was initiated in 1998, the FDA has processed 638 GRAS notices, compared to the previous decade where the agency issued 25 GRAS affirmation petitions.

FDA can take action against food substances that fail to qualify.

When a use of a substance does not qualify for the GRAS exemption, that use of the substance is subject to the premarket approval mandated by the FD&C Act. In such circumstances, the FDA can take enforcement action to stop distribution of the food substance and foods containing it on the grounds that such foods are or contain an unlawful food additive.

The FDA points to its treatment of partially hydrogenated oils (PHOs) and caffeinated alcoholic beverages as evidence the voluntary GRAS pilot notification program was, and will continue to be, effective.

The agency states that there "is no longer a consensus among qualified experts that PHOs are GRAS for any use in human food," and that it "informed the companies who were marketing these caffeinated alcoholic beverages that caffeine, as used in the companies' products, is an unsafe food additive, and therefore the products are adulterated."

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