Food Allergen Labeling and Reporting

OMB Control No. 0910-0792 – Request for Non-substantive Change

The Food and Drug Administration (FDA) finalized the attached guidance document entitled, "*Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5)*," which explains FDA's current thinking on a number of issues related to the labeling of food allergens, including requirements in the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) and the Food Allergy Safety, Treatment, Education, and Research Act of 2021 (FASTER Act). The guidance document adds sesame as a "major food allergen" as the definition was amended by the FASTER Act. The additional burden attributable to required declarations and/or associated requests for exemption as they pertain to foods that include sesame, as well as the draft guidance, have been previously considered and approved as a revision during the last renewal cycle for this collection (Conclusion date 6/4/2024). Thus, we have not adjusted our burden estimate as a result of this action.