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ALERTS

Food, Drug And Device Law Alert - FDA Issues Draft Guidance On Convening Panels To Review Food Safety

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The Food and Drug Administration (FDA) recently issued a draft guidance titled "Best Practices for Convening GRAS Panels: Guidance for Industry." All comments on the draft guidance, which addresses evaluation of food ingredients generally recognized as safe (GRAS), must be submitted by Jan. 16, 2018.

A GRAS panel is "a panel of qualified experts who independently evaluate whether the available scientific data, information, and methods establish that a substance is safe under the conditions of its intended use in human food or animal food as part of an evaluation of whether adding that substance to food is lawful under the GRAS provision of the FD&C Act." If a substance is determined to be GRAS, it may be used as an ingredient in food without undergoing the FDA's otherwise mandatory premarket review.

The draft guidance includes several specific recommendations related to the use of GRAS panels. On the topic of selecting GRAS panel members, things the FDA recommends, among other things:

- The organizer of the GRAS panel, or the attorney, agent, or employees of the organizer or of the proponent of GRAS status, should not be members of a GRAS panel. If such an individual has specialized experience that could be helpful to a GRAS panel, the proponent or organizer could consider whether that individual could act as a scientific advisor to the GRAS panel by providing factual information to the GRAS panel without participating in any of the GRAS panel's deliberations.
- The organizer or proponent should consider individuals with expertise that reflects the physical, chemical, and biological properties of the food substance and the scientific questions that arise in relation to the conditions of its intended use. At a minimum, a GRAS panel should include members with expertise in chemistry or biochemistry, toxicology, and exposure assessment.
- The organizer or proponent should determine the total number of GRAS panel members, as well as the number of GRAS panel members with the same expertise, based on the substance, the complexity of the scientific issues associated with the conditions of its intended use, and the available data and information about the substance

The guidance also describes and asks for industry comment on FDA

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recommendations for:

- assessing and managing procedural issues related to the organization and deliberations of a GRAS panel
- assessing and managing conflicts of interest, and the appearance thereof, of potential GRAS panel members
- the information provided to GRAS panel members
- documenting the deliberations and conclusions of a GRAS panel

Additional detail on the recommendations from the draft guidance for these topics follows.

Organization and deliberations of a GRAS panel:

- The organizer or proponents should prepare a written GRAS panel policy addressing the potential for bias that could occur through procedures associated with the organization and deliberations of a GRAS panel.
- The proponent take appropriate steps to avoid influencing the deliberations of the GRAS panel – e.g., by formulating the charge to the panel in neutral, unbiased language; limiting communication with the GRAS panel to the minimum necessary to manage the affairs of the GRAS panel efficiently and effectively; and then awaiting the outcome.

Conflicts of interest, and the appearance thereof, of potential GRAS panel members:

- A written GRAS panel policy should assess the potential for conflict of interest and the appearance thereof during the selection and vetting of GRAS panel members.
- A written GRAS panel policy should be publicly available and provide for transparency by allowing outside parties to assess the process used to assess and manage conflicts of interest and the appearance thereof in members of the GRAS panel.
- A written GRAS panel policy should include a process for identifying competing interests, including conflicts of interest and the appearance thereof, as well as strategies for managing them.
- A written GRAS panel policy establish pre-existing criteria for evaluating the significance of conflicts of interest and the appearance thereof.

Information provided to GRAS panel members:

- The proponent or organizer should minimize the amount of non-public information provided to a GRAS panel.
- An exception to the above recommendation relates to data and information that could raise a question about the safety of the substance under the conditions of its intended use. The data and

information that the proponent or organizer provides to a GRAS panel should include a description of all data and information that could raise such a safety question, regardless of whether those data and information are publicly available.

Documenting the deliberations and conclusions of a GRAS panel:

- Clear and explicit documentation of: (1) The available data and information that the GRAS panel reviewed; (2) how the GRAS panel handled its deliberations; and (3) the basis for the conclusion of the GRAS panel.
- Each member of the GRAS panel should identify the particular data or information that form the basis for his or her opinion on whether the intended use of the substance is safe, both during deliberations and in any written GRAS panel report.
- GRAS panel members should avoid filling a gap in the available data and information through theoretical considerations and relevant experience.
- The proponent or organizer should establish and implement a mechanism to demonstrate that the deliberations of a GRAS panel and any GRAS panel report broadly reflect the views of the scientific community knowledgeable about the safety of substances directly or indirectly added to food in addition to the individual views of each panel member.

The draft guidance concludes with considerations for when a GRAS notice is submitted to the FDA, and for when one is not submitted, and for payment of honoraria to GRAS panel members.

For more information, please contact the Barnes & Thornburg LLP attorney with whom you work or the chair of the firm's Food, Drug and Device Practice Group, Lynn Tyler at (317) 231-7392 or lynn.tyler@btlaw.com.