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FDA Proposed Rule: Investigational New Drug Applications: Exemptions for Clinical Investigations to Evaluate a Drug Use of a Product Lawfully Marketed as a Conventional Food, Dietary Supplement or Cosmetic

Federal Register Docket Number: FDA-2019-N-2650

Comments Closed: March 9, 2023

Final Rule Pending – Anticipated date of publication in FDA's Unified Agenda was April 2024

On December 9, 2022, the FDA issued a proposed rule of significance to institutions and IRBs that conduct/review research involving conventional foods, dietary supplements, and cosmetics. The proposed rule seeks to add exemptions to exempt certain studies that involve the investigation of such products as a drug (e.g., to evaluate its potential for the cure, mitigation, treatment, or prevention of disease).

Under the proposed rule, certain studies for which the FDA historically may have elected to exercise enforcement discretion on a case-by-case basis, would now be eligible for one of two types of IND exemptions: (1) a self-determined exemption, or (2) an FDA-determined exemption.

The self-determined exemption would apply to investigations to evaluate a potential drug use of a lawfully marketed conventional food, dietary supplement, or cosmetic when certain conditions are met, including:

- The investigation is not intended to support a drug development plan for the product (including a future IND or application for marketing approval) or a labeling change that would cause the lawfully marketed product to become an unlawfully marketed drug;
- The investigation is conducted in compliance with the requirements for IRB review and informed consent;
- The investigation is conducted in compliance with the regulations governing promotion and commercial distribution of investigational drugs;
- The route of administration of the product in the investigation is the same as that of the lawfully marketed product; and
- The investigation meets certain criteria designed to protect the health, safety, and welfare of subjects.

Additional criteria related to the final bullet point are also described in the proposed rule and include factors such as age, underlying conditions, treatment restrictions, greater than minimal risk procedures, consistency with labeling, and risk.

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The FDA-determined exemption could be requested "when the investigation meets the self-determined exemption criteria except for one or more of the subject health, safety, and welfare criteria, but the sponsor has concluded that the investigation nevertheless does not present a potential for significant risk to subjects." Requests for such exemptions would be submitted by sponsors, or sponsor-investigators, to the FDA who in turn "would grant an exemption if we found that the investigation did not present a potential for significant risk (or decrease the acceptability of the risks) to the health, safety, or welfare of subjects." The FDA could also use this mechanism to exempt a study from the IND requirements, rather than issue an enforcement discretion letter, when studies that have been submitted for an IND qualify for exemption. The FDA would also have the authority to revoke the exemption when new information would change the original determination.

Importantly, studies under an IND exemption would still need to comply with 21 CFR part 50 and 56 (i.e., these would still be considered FDA-regulated studies). There are also limitations on promotion, test marketing, and commercial distribution.