Contains Nonbinding Recommendations

Draft - Not for Implementation

Guidance for the Public and FDA Staff on Convening Advisory Committee Meetings

Draft Guidance

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For questions regarding this draft document, please contact the Advisory Committee Oversight and Management Staff at 301-827-1220.

U.S. Department of Health and Human Services
Food and Drug Administration

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U.S. Department of Health and Human Services
Food and Drug Administration

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This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights on any person and does not operate to bind FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the appropriate FDA staff. If you cannot identify the appropriate staff, call the appropriate number listed on the title page of this guidance.

I. Introduction

This draft guidance provides guidance on factors FDA considers in deciding whether to refer a matter to an advisory committee for consideration.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or

statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background

Consistent with the Federal Advisory Committee Act, FDA has established advisory committees when it is in the public interest in connection with the performance of duties imposed on the agency by law. FDA also has established some advisory committees as a result of specific statutory mandates. FDA's advisory committees provide independent expert advice to the agency on a range of complex scientific, technical, and policy issues. An advisory committee meeting also provides a forum for a public hearing on important matters. Although advisory committees provide recommendations to FDA, FDA makes the final decisions.

The procedures and rules that govern FDA's advisory committee program are set forth in general terms in the agency's regulations.[1] To enhance the transparency of FDA's advisory committee program, the agency is publishing this document to provide its current thinking on factors FDA considers in deciding whether to bring a matter to an advisory committee.

FDA seeks input from advisory committees on a broad scope of complex issues related to the products it regulates. These issues typically relate to a specific food or medical product, a class of foods or medical products, the development and implementation of a specific regulatory program, or the development and implementation of a regulatory policy. In some cases, FDA refers such matters to advisory committees when required to do so by statute. Advisory committee meetings also facilitate public discussion of important topics and provide a means for the public to provide comments to the agency. FDA recognizes that advisory committee meetings demand significant resource commitments by advisory committee members, sponsors and other public participants, as well as for the FDA itself, and should be used for important matters.

This guidance sets forth FDA's current thinking on factors FDA considers in deciding whether to bring a matter to an advisory committee. While the policy set forth below generally applies to all components in the agency, it is important to note that different FDA-regulated products present different scientific issues and different risks; these differences are reflected in different legal requirements and different practices in the respective centers in FDA. This guidance is not intended to supersede or displace center-specific procedures on this subject insofar as those separate procedures remain consistent with the policy described in this document or insofar as those procedures are required by law.

[1] 21 CFR Part 14: Public Hearing Before a Public Advisory Committee.

III. Policy

A. Considering when to Convene a Meeting

In most instances, FDA has discretion to consider whether to refer a matter to an advisory committee for consideration.[2]

1. Factors:

In those instances in which FDA is not legally compelled to refer a matter to an advisory committee, it may nevertheless choose to do so voluntarily. When considering whether to convene such a meeting, FDA should consider the following three factors:

(a) Is the matter at issue of such significant public interest that it would be highly beneficial to obtain the advice of an advisory committee as part of the agency's regulatory decision-making process?

(b) Is the matter at issue so controversial that it would be highly beneficial to obtain the advice of an advisory committee as part of the agency's regulatory decision-making process?

(c) Is there a special type of expertise that an advisory committee could provide that is needed for the agency to fully consider a matter?

In the event that one or more of these factors is met, the matter at issue should generally be referred to an advisory committee.

Conversely, FDA personnel should generally refrain from referring a matter to an advisory committee if none of the factors is met. This policy is grounded in our recognition that FDA has limited resources and that referring a matter to an advisory committee requires a substantial expenditure of resources and time. By prioritizing matters according to the factors above, we help ensure that the finite resources of our advisory committee program are devoted to consideration of the most important matters, including those matters in which the agency would most benefit from the advice of outside experts.

2. Examples of Scenarios in which One or More of the Factors are Often Met:

[2] The Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 321 et seq.) calls for FDA to refer matters to advisory committees for recommendations in some circumstances. *See, e.g.*, FDCA §§ 505A(i)(2)(A), 513(b)-(c), and 520(l)(2). This guidance does not address those types of committee meetings.

FDA regulates a broad range of products and conduct, which means the preceding factors must be evaluated in many different contexts. To provide more clarity on when to hold meetings, the bullets below identify different kinds of scenarios in which one or more of the factors are often met. The scenarios identified in the bullets may apply in pre-market situations, post-market situations, or both. They may also pertain to questions about a specific product or questions about a broad, cross-cutting policy.

- FDA is evaluating a first-of-a-kind, first-in-class medical product for human use.
- FDA is evaluating a first-in-class antimicrobial for use in food-producing animals.
- FDA is evaluating a medical product for a significant new indication.
- FDA is evaluating a novel product or use of new technology.
- FDA is evaluating a medical product that involves a significant diagnostic, therapeutic, or preventative advance.
- FDA's assessment of the risk/benefit ratio of a product or class of products is likely to be controversial or it appears that the risks and benefits are of similar magnitude, especially where the products may have a narrow therapeutic effect.
- FDA has significant safety concerns about a class of products. This scenario includes such concerns in pre- or post-market situations (e.g., significant safety concerns relating to the pre-market review of a medical product regulated by FDA, or significant safety concerns relating to the post-market review of such a medical product, including significant concerns about adverse event reports or other data that signal a potential safety issue).
- FDA has significant questions or concerns about the use of a product in certain subpopulations (e.g., pediatric dosing or a newly discovered contraindication)
- FDA has significant questions or concerns about a study, including a clinical trial, post-market assessment, or product development protocol (PDP). The questions or concerns may relate to any aspect of such a study, including human subject protection, novel endpoints or surrogates, the study's design, or its results.
- FDA personnel have a significant difference of scientific opinion on a complex matter, for example on the interpretation of data or judgments about the risk/benefit ratio of a regulated product.
- FDA has questions or concerns involving the intersection of several scientific disciplines.

- FDA is seeking outside expertise on scientific techniques or research.

- FDA is evaluating whether to switch a product class from one regulatory status to another (e.g., switching a class of drug products from prescription to over-the-counter status.)

- FDA has significant questions or concerns regarding the development or implementation of a regulatory policy or guidance document.

- FDA wants independent, outside evaluation of the quality, relevance, or productivity of an agency communication program or research program.

C. First-of-a-Kind, First-in-Class Medical Products

Under section 505(s) of the Federal Food, Drug, and Cosmetic Act, before approving a drug no active ingredient of which has been approved, FDA must either refer that drug to an advisory committee or provide in the action letter for the drug a summary of the reasons why FDA did not refer the drug to an advisory committee before approval.

To help FDA personnel follow this guidance, and to help improve consistency between the product centers, FDA intends to adopt a similar policy across the agency for all first-of-a-kind, first-in-class medical products for human use. Accordingly, when FDA is evaluating any first-of-a-kind, first-in-class medical product for human use, FDA should either refer the product to an advisory committee or provide in the action letter for that product a summary of the reasons why it did not refer the product to an advisory committee before approval. As set forth above, the decision whether to refer such a medical product to an advisory committee should be based on the factors set forth in section III.A.1.

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