IDE Refuse to Accept Procedures #D94-1 (blue book memo) (Text Only)

This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

IDE Memorandum #D94-1

Deputy Director, Office of Device Evaluation (HFZ-400)

IDE Refuse to Accept Procedures

ODE Review Staff

Purpose

The purpose of this memorandum is to establish procedures under which an IDE that does not meet a minimum threshold of acceptability will not be accepted for substantive review and approval.

Background

The Office of Device Evaluation (ODE) receives approximately 225 original Investigational Device Exemptions (IDE) submissions each year. Many of these applications are incomplete or grossly inadequate, i.e., they fail to contain information clearly required under the regulations and they fail to contain the components necessary to allow substantive review. An IDE application that is missing any of the elements of 21 CFR 812.20, is technically an incomplete application and, therefore, not subject to the 30 day review clock. As a means to employ ODE resources more effectively, these procedures are being implemented to ensure that IDEs meet a minimum threshold of acceptability; otherwise, ODE will refuse to accept the application. These procedures will benefit both FDA and IDE sponsors.

A primary goal in establishing these "Refuse to Accept Procedures" for IDEs is to improve the use of our review resources by ensuring that they are focused on the review of reasonably complete and well-supported applications. Often, during initial substantive review, ODE has found that crucial information necessary to make a decision to approve or disapprove an IDE has been omitted. When making a decision to accept or not to accept an application, ODE will identify those applications in which sufficient information is submitted to allow a decision on the approvability of the investigation (i.e., the application is complete on its face). By establishing these procedures with criteria for completeness of an application that are clear,

consistent, and available to sponsors, they will know what is expected of them for each submission and device they intend to investigate. Sponsors will be likely to comply with the established criteria to speed the time to substantive review of and a final decision on their application.

These procedures are based upon the Management Action Plan (MAP) initiative issue paper entitled "Center for Devices and Radiological Health's Investigational Device Exemptions (IDE) Refuse to Accept Policy." This Blue Book Memorandum embodies the guidance procedures flowing from that issue paper and hereby replaces that document as the policy of ODE. Attached to the MAP issue paper was a document entitled "IDE Refuse to Accept Criteria" and an accompanying checklist. As described below, these criteria and the checklist will be used by ODE reviewers in applying these guidance procedures to the review of incoming IDEs.

In general, there are three bases for refusal to accept an IDE:

1. An approved IDE is not required for the investigation.

2. The application omits a section of the IDE required under the IDE regulation, 21 CFR Part 812.

3. The application fails to address generally accepted scientific and professional principles governing the conduct of clinical trials or scientific/technical issues clearly described in general, device-specific, and crosscutting guidance documents made publicly available by FDA.

The checklist that accompanies the "IDE Refuse to Accept Criteria" is a general checklist. Divisions may modify or supplement this general checklist based on available guidance documents appropriate to their specific device areas. Division guidance documents should be promulgated wherever needs are identified. Guidances should provide specific details about what is expected and acceptable for all components of the submissions. Each product specific guidance should include a checklist to be used by a) the applicant in preparing the submission and b) reviewers during the initial evaluation to consider accepting the application for full review. Checklists should also be prepared for existing guidelines. This will save time and provide

consistency across submissions. Also, emphasis should be placed on improved communication with industry.

In addition to the copies that are being made available to ODE reviewers, the document, "IDE Refuse to Accept Criteria" and any device specific guidance documents and checklists developed by the divisions are being made available to manufacturers and other members of the public by the Center's Division of Small Manufacturers Assistance.

Procedures

This guidance memorandum will be implemented by the review divisions within the Office of Device Evaluation utilizing the following procedures. The specific timeframes are goals that will be met to the extent permitted by available resources.

1. Processing

   a. The ODE Document Mail Center (DMC) will log in and jacket the IDE and forward it to the IDE Staff. The IDE Staff will conduct a preliminary review to verify that the submission is an IDE, and that it is administratively complete. If grossly administratively incomplete, the IDE Staff will issue an incomplete letter. If the submission is administratively complete, it will be forwarded to the appropriate review division within 2 days of receipt of the application in the DMC or as quickly as available resources allow.

   b. A designated reviewer (Branch Chief, Reviewer, CSO, CST), using the IDE Refuse to Accept Criteria and checklist, and other appropriate device specific checklists, will determine whether the IDE is sufficiently complete to allow substantive review. The division should consult with the Program Operations Staff (POS) on any decision that is particularly difficult or controversial.

   c. Refuse to Accept recommendation(s) will be forwarded to the appropriate supervisor for concurrence within 10 days of DMC's receipt.

   d. If an application is found to be sufficiently complete to

allow substantive review, the IDE will be placed into the queue for substantive review.

e. If an application is found to be insufficiently complete to allow substantive review, a Refuse to Accept letter will be prepared, in coordination with the POS Staff, for the Division Director's signature. The Refuse to Accept letter, detailing the omissions or inadequacies that led to the decision not to accept the application, will issue within 15 days of receipt of the original IDE. The letter will clearly state whether a complete, new application must be submitted or specify which portion of the application must be provided if the sponsor wishes to pursue the investigation.

2. Industry Inquires

In the event that the sponsor has questions regarding the Refuse to Accept letter, the sponsor may contact the appropriate Division Director, via letter, telephone, or telefax, regarding the decision.

3. Monitoring

The implementation of the IDE Refuse to Accept Procedures will be reviewed by the Office of the Director, ODE, at regular intervals, approximately every 90 days, to determine the number of incomplete and/or inadequate applications not accepted, the consistency with which the criteria are applied among and within divisions, further necessary refinements to the process, and the overall impact on the IDE program.

Effective Date

This memorandum effective immediately.

Susan Alpert, Ph.D., M.D.

More in Guidance Documents (Medical Devices and Radiation-Emitting Products)

More in Guidance Documents (Medical Devices and Radiation-Emitting Products) (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm)

Cross-Center Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081752.htm)

Office of Compliance Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070269.htm)

Office of the Center Director Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110228.htm)

Office of Communication and Education Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070271.htm)

Office of Device Evaluation Final Guidance 2010 - 2016 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm198577.htm)

Office of Device Evaluation Final Guidance 1998 - 2009 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070272.htm)

Office of Device Evaluation Final Guidance 1976 - 1997 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080283.htm)

Office of In Vitro Diagnostics and Radiological Health Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070274.htm)

Office of Surveillance and Biometrics Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070275.htm)

Office of Science and Engineering Laboratories Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070277.htm)

Draft Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm407274.htm)

Radiation-Emitting Products Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm283507.htm)

Withdrawn Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm425025.htm)