GUID D94-1: IDE REFUSE TO ACCEPT PROCEDURES; MAY 20, 1994

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IDE Memorandum #D 94-1

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Memorandum

Date MAY 20 1994

From Deputy Director, Office of Device Evaluation (HFZ-400)
>
Subject IDE Refuse to Accept Procedures

To 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