GUID D93-1: OVERDUE IDE ANNUAL PROGRESS REPORT PROCEDURES; JULY 23, 1993

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IDE Memorandum #D 93-1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

IDE Memorandum #D93-1

Date JUL 23 1993

From Deputy Director, Office of Device Evaluation

Subject Overdue IDE Annual Progress Report Procedures

To ODE Review Staff

Purpose

To establish a procedure for the follow-up on sponsor failure to file IDE annual reports.

Background

The IDE regulation requires a sponsor of an IDE application to submit to FDA, on an annual basis, a progress report (as outlined in the "Suggested Format of IDE Progress Reports"). The annual progress reports allow FDA to determine whether there are any apparent risks to the subjects enrolled in an ongoing clinical investigation throughout its course.