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Goals and Initiatives for the IDE Program 7/12/95 (D95-1)

IDE Memorandum - #D95-1

Office of Device Evaluation (HFZ-400)

Goals and Initiatives for the IDE Program

ODE Review Staff

Purpose

The purpose of this memorandum is to establish procedures for the efficient review of IDEs and to identify performance goals for the IDE Program.

Background

The Office of Device Evaluation (ODE) has traditionally approved approximately one third of the original investigational device exemption (IDE) applications in the first 30 day review cycle. In recent times (fiscal years (FY) 1993 and 1994), however, only 25% of the original IDE applications were approved during this initial review period. In addition, the average total time from receipt of the application to approval increased to 242 days after averaging 178 days for the last 5 years.

The reasons for non-approval may be summarized as relating to inadequate characterization of the device being investigated, poorly designed clinical trials, and inadequate subject protection measures. In all cases, ODE's intent has been to improve the quality of the information derived from the

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Best regards,
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