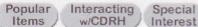
This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of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

U.S. Food and Drug Administration - Center for Devices and Radiological Health)

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



Interest Premarket Postmarket

Rad. Topic Health Index

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

Vintage Documents from Clinical Device Group

Is this the document you are looking for? Just email us **here** to obtain the entire copy of the FDA July 1995 Blue Book Memo D95-1 "Goals and Initiatives for the IDE Program," free and with our compliments.

Best regards, Nancy J Stark, PhD President, Clinical Device Group Inc

Click on whitepapers to opt-in to our whitepapers mailing list.