GUID D89-1: REVIEW OF IDES FOR FEASIBILITY STUDIES

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IDE Guidance Memorandum No. #D 89-1 May 17, 1989

The attached guidance details the purpose and procedure for the review of IDE applications for feasibility studies involving limited numbers of human subjects. It was developed through review of a citizen petition submitted to the agency requesting amending the IDE regulation to provide for such studies, by review of ODE's procedures in reviewing early-phase studies, and from input from ODE Division Directors and other staff. The concepts and procedure outlined in the guidance should be implemented immediately.

Attachment

GUIDANCE ON THE REVIEW OF INVESTIGATIONAL DEVICE EXEMPTIONS (IDE) APPLICATIONS FOR FEASIBILITY STUDIES

INTRODUCTION

On November 21, 1984, the American Society for Artificial Internal Organs (ASAIO) submitted a citizen petition requesting FDA to amend the investigational device exemptions (IDE) regulation to allow limited clinical investigations of significant risk devices to be subject to less than the full IDE requirements. FDA may not be able to accept the petition in its entirety but recognizes the importance of providing flexibility in the review of IDE applications for feasibility studies, as long as the subjects' safety and welfare are ensured. While CDRH has been exercising its discretion in the review and approval of feasibility studies, it has become apparent that this procedure needs to be formalized in order to be consistently applied by the reviewing divisions and to advise the research clinical community of these procedures.

It is relatively easy for a sponsor to identify a feasibility study by merely pointing out that the study involves a new device or a new technology and will involve only a few human subjects. It is much more difficult to establish the criteria for relief from specific requirements of IDE regulation while assuring that patients are not placed at unreasonable risk. Relief can only be granted on a