Center for Devices and Radiological Health

Guidance on IDE Policies and Procedures

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IDE Staff
Office of Device Evaluation
Center for Devices and Radiological Health

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Comments and suggestions may be submitted at any time for Agency consideration to the IDE Staff, HFZ-403, Office of Device Evaluation, 9200 Corporate Boulevard, Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact the IDE Staff at (301) 594-1190. This guidance replaces the guidance entitled, "Clarifications of IDE Policies and Procedures" (September 13, 1991).

IDE POLICIES AND PROCEDURES

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Chapter I
General IDE Policies

This document is intended to provide guidance[1] to Office of Device Evaluation (ODE) reviewers on issues frequently encountered during the review of Investigational Device Exemptions (IDE) applications. In the first chapter of this document, general issues pertinent to the review of IDE applications are presented. This is followed by a discussion in Chapter II of several new regulations which affect the IDE Program. Finally in Chapter III, the four main mechanisms by which unapproved devices may be made available to patients faced with life-threatening or serious conditions are discussed.

In some cases, rather than repeating information that has been previously provided in ODE Blue Book Memoranda or other guidances, only summary information is presented. Whenever possible, however, specific procedures to be followed are identified, including references to appropriate ODE Blue Book Memoranda and IDE boilerplate letters.

Pre-IDE Process

In order to facilitate the initiation of clinical trials under the IDE regulation, the Food and Drug