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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Date: SEP 15 1995

From: Office of Device Evaluation (RFZ-400)

Subject: Implementation of the FDA/HCFA Interagency Agreement Regarding Reimbursement Categorization of Investigational Devices

To: ODE Review Staff

Purpose

The purpose of this memorandum is to establish procedures for fulfilling FDA's responsibilities as defined in the FDA/HCFA Interagency Agreement (IA) pertaining to the reimbursement of investigational devices.

Background

According to the statute governing the Medicare program (Section 1862 (a)(1)(A) of the Social Securities Act), the Health Care Financing Administration (HCFA) is permitted to reimburse for medical services and products that are deemed "reasonable and necessary" for the diagnosis or treatment of an illness or injury, or to improve the functioning of a malformed body member. The Medicare program has historically interpreted the statutory terms "reasonable and necessary" to mean that a service or medical device must be safe and effective, medically necessary and appropriate, and not experimental in order to qualify for reimbursement. For Medicare coverage