DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Memorandum

Date April 24, 1987

General Program Memorandum #87-1
Date: April 24, 1987

From Director
Office of Device Evaluation

Subject Tripartite Biocompatibility Guidance

To ODE Review Staff

Purpose

A copy of the Tripartite Biocompatibility Guidance for Medical Devices, dated September 1986, is attached. The purpose of this guidance is to establish an approach for the evaluation of the toxicity of medical devices. This guidance is intended to assist manufacturers and government health authorities to anticipate the information needed for such evaluation. ODE is in the process of developing further guidance that expands on the Tripartite guidance as it applies to the review of submissions made to ODE.

Background

The Tripartite Subcommittee for Medical Devices is comprised of the senior officials of the medical device authorities of the United States, the United Kingdom, and Canada. During its September 1984 meeting, the Subcommittee decided that development of a common approach to toxicity testing would be highly desirable. The Subcommittee established the Toxicology Subgroup to work toward this goal. The guidance document produced by the subgroup, Tripartite Biocompatibility Guidance for Medical Devices, has been distributed to each of the three countries with the common understanding that it would be circulated in the respective national communities for comment and use "as appropriate." Our Center's Toxicology Committee will be asked to circulate the guidance among appropriate scientific and industry groups for informal comment. In the interim, ODE will utilize this guidance.

Scope and Application of the Guidance

The Tripartite guidance enunciates fundamental principles for toxicity evaluation of medical devices and provides a rational framework for their application. The application of these principles envisions the