PART I

BACKGROUND

This compliance program provides guidance to FDA field and center staffs for the inspections and administrative/enforcement activities related to the Quality System (QS) regulation (21 CFR Part 820), the Medical Device Reporting (MDR) regulation (21 CFR Part 803), the Medical Device Tracking regulation (21 CFR Part 821), the Corrections and Removals regulation (21 CFR Part 806), and the Registration and Listing regulation (21 CFR Part 807). This compliance program supersedes the program of the same name which was issued on October 1, 2000.

This compliance program encompasses five regulations for inspecting medical device firms. Under the QS regulation, manufacturers are expected to control their devices from design stage through post-market surveillance. Manufacturing processes, such as sterilization, are required to be implemented under appropriate controls. The MDR, Tracking, and Corrections and Removals regulations involve activities with which manufacturers and importers are required to comply after the devices are distributed. This compliance program provides specific guidance for each. It also requires coverage for the Registration & Listing regulation.

A. THE QUALITY SYSTEM (QS) REGULATION

Manufacturers establish and follow quality systems to help ensure that their products consistently meet applicable requirements and specifications. The quality systems for FDA-regulated products (food, drugs, biologics, and devices) are known as CGMP's. CGMP requirements for devices in part 820 (21 CFR part 820) were first authorized by section 520(f) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(f)), which was among the authorities added to the act by the Medical Device Amendments of 1976. Under section 520(f) of the act, FDA issued a final rule in the Federal Register of July 21, 1978 (43 FR 31 508), prescribing CGMP requirements for the methods used in, and the facilities and controls used for the manufacture, packing, storage, and installation of medical devices. This regulation became effective on December 18, 1978.

The Safe Medical Devices Act of 1990 (the SMDA), enacted on November 28, 1990, amended section 520(f) of the act, providing FDA with the authority to add preproduction design controls to the CGMP regulation. This change in law was based on findings that a significant proportion of device recalls were attributed to faulty design of product. The SMDA also added new section 803 to the act (21 U.S.C. 383) which, among other things, encourages FDA to work with foreign countries toward mutual recognition of CGMP requirements. FDA undertook the revision of the CGMP regulation to add the design controls authorized by the SMDA to the CGMP regulation, as well as because the agency believed that it would be beneficial to the public and the medical device industry for the CGMP regulation to be consistent, to the extent possible, with the requirements for quality systems contained in applicable international standards. FDA published the revised CGMP requirements in the final rule entitled “Quality System Regulation” in the Federal Register of October 7, 1996 (61 FR 52602). This regulation became effective on June 1, 1997 and remains in effect.

B. THE MDR REGULATION

The first Medical Device Reporting (MDR) regulation became final on December 13, 1984. As a result of changes mandated by the Safe Medical Devices Act (SMDA) of 1990, and the Medical Device Amendments of 1992, the 1984 MDR regulations (21 CFR 803 & 807) were revised and published on December 11, 1995. The FDA Modernization Act of 1997 made additional changes and a revised MDR regulation was proposed in May 1998. The final revised MDR regulation was published in the Federal Register on January 26, 2000. The latest version of MDR regulation includes reporting requirements for manufacturers, user facilities, and importers. MDR reporting for medical device distributors (except importers) was revoked by the FDA Modernization Act of 1997. Distributors are, however, still required to maintain complaint records, per 21 CFR 803.18(d)(1-3).

21 CFR Part 803 requires manufacturers of medical devices, including in vitro diagnostic devices, to report to FDA whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices:

1. may have caused or contributed to a death or serious injury or,
2. has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

NOTE: Importers (initial distributors) of medical devices are subject to 21 CFR Part 803 published in the Federal Register on January 26, 2000, and effective March 27, 2000.

C. THE MEDICAL DEVICE TRACKING REGULATION

Under the authority of section 519(e) of the Act, the agency may issue a written tracking "order" that tells a manufacturer to implement a tracking program that meets the requirements of 21 CFR Part 821. Devices subject to tracking may include those that are permanently implanted or life sustaining/life supporting devices that are used outside a device user facility. These devices are considered reasonably likely to cause serious adverse health consequences if they fail. The regulation is intended to ensure that in the event of a recall or safety alert, a tracked device can be traced by the manufacturer from the device manufacturing facility to the end user or patient.

D. THE CORRECTIONS AND REMOVAL REGULATION

The Corrections and Removal regulation requires manufacturers, and importers to report promptly to FDA any corrections or removals of devices being undertaken to reduce risk to health.

E. THE REGISTRATION AND LISTING REGULATION

The Registration and Listing regulation requires manufacturers and foreign exporters to register and list their devices; and importers to register. (See Part III)