SUBJECT: Recognition of Inspection of Manufacturers of Medical Devices

(FDA Agreement No. 225-86-6000)

(Previously CPG 7156p.02)

Notes:

The FDA contact for this MOU is Lillian Gill, HFZ-300

Tel. No. 301-594-4692

This MOU is effective indefinitely.

MEMORANDUM OF UNDERSTANDING

Between The

DEPARTMENT OF HEALTH AND SOCIAL SECURITY
OF THE UNITED KINGDOM

And The

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
OF THE UNITED STATES OF AMERICA

For The

MUTUAL RECOGNITION OF INSPECTIONS OF
MANUFACTURERS OF MEDICAL DEVICES

PREAMBLE

The Food and Drug Administration (FDA) and the Department of Health and Social Security of the United Kingdon and Northern Ireland (DHHS):

Considering that the rapid development of new medical devices necessitates strict quality control of their manufacture; and

Considering that official inspection is necessary to ensure such manufacturing control;

Have agreed as follows:

SECTION I

A. FDA and DHSS will exchange such information as is necessary for the mutual recognition of inspections related to medical devices manufactured in one country and intended for import into the other;

B. Exchange information about methods for conducting appropriate and effective inspections;

C. Promote the mutual training of investigators;

D. Promote cooperation between the parties to facilitate the application of this agreement;

E. Develop or amend notes for the explanation of the provisions of this agreement; and

F. Make recommendations on any question relating to the

Notes:

implementation of this memorandum of understanding or make proposals for its amendment.

PARTICIPATING PARTIES

A. Department of Health and Social Security, Elephant and Castle, London, England.

B. Food and Drug Administration, Department of Health and Human Services, 5600 Fishers Lane, Rockville, MD 20857.

LIAISON OFFICERS

A. For DHSS:

Deputy Director of Scientific and Technical Services,
14 Russell Square, London,
England WC1B5EP,
01-636-6811 X3049.

B. For FDA:

Director, Division of Compliance Programs (HFZ-330),
Center for Devices and Radiological Health,
8757 Georgia Ave.,Silver Spring, MD 20910,
301-427-7122.

B.
Director, Division of Compliance, HFZ-300 (Currently Lillian Gill)
2098 Gaither Road, Rockville, MD 20850

Tel. No. 301-594-4692

SECTION II.

A. DHSS will provide information to FDA only with respect to United Kingdom (UK) medical device manufacturers who are required to comply with the provisions of the Federal Food, Drug, and Cosmetic Act of the USA.

B. FDA will provide information to DHSS only with respect to USA medical device manufacturers who have applied for registration under the DHSS Manufacturer Registration Scheme.

SECTION III .

A. Upon the request of either FDA or DHSS (the parties) and in accordance with Section II, the other party will provide:

1. Information regarding the standards of manufacturing practice in a particular firm; and

2. Answers to supplementary questions which are relevant to the quality assurance procedures used in the manufacture of medical devices.

Notes:

B. Information provided under the agreement will not extend to financial and commercial matters, research matters, proprietary design matters, technical "know how" or personal data other than those relating to the duties of the persons concerned except where this kind of information is necessary to assess compliance with applicable quality assurance requirements.

SECTION IV.

The information provided will be based on inspections carried out by (or on behalf of) either party together with any consequent action. Such inspections will normally be those made in the course of the application of the established system of control.

SECTION V.

A. Before providing information about any firm, the inspecting party will inform the manufacturer of its intention to do so.

B. A UK manufacturer may withhold consent to disclose specific information relating to the firm. In such a case DHSS will notify FDA that the manufacturer has not consented to the release of certain information.

C. A USA manufacturer may withhold consent to disclose an unpurged inspectional report relating to the firm. In such cases, FDA will notify DHSS of the refusal.

SECTION VI.

A. Each party will normally recognize inspections carried out by the other under the conditions of Section III as satisfying its own requirements for the inspection of manufacturers of medical devices, but each party reserves the right to carry out its own inspection if the party considers it necessary.

B. This right will be exercised only after full discussion between the parties, with the party exercising the right explaining why its own inspection is considered necessary.

SECTION VII.

If either party discovers in the course of its inspection duties,or through other means, particular circumstances which cause a medical device to be of imminent and serious danger to the public, it will immediately communicate its findings to the other party.

Notes:

SECTION VIII.

Officials of FDA and DHSS shall meet whenever necessary, but not less than once a year in order to:

A. Make recommendations and proposals for standards of current good manufacturing practice;

B. For the purpose of this agreement "medical device" means any instrument, apparatus, implement, appliance, implant or other such related article which is intended for use in the treatment of humans, in contraception, or in diagnosis or that otherwise is a "device"under the Federal Food, Drug, and Cosmetic Act of the United States of America (USA).

SECTION IX.

This agreement will become effective upon acceptance by both parties and will continue in effect indefinitely. It may be revised by mutual written consent or terminated by either party by a 60-day advance written notice to the other party.

APPROVED AND ACCEPTED FOR THE DEPARTMENT OF HEALTH AND SOCIAL SECURITY, THE UNITED KINGDOM

By: /s/

Title: Director of Scientific and Technical Services

Date: June 4, 1986

APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES, UNITED STATES OF AMERICA

By: Joseph P. Hile /s/

Title: Associate Commissioner for Regulatory Affairs

Date: June 3, 1986

The ACRA is currently Mr. Ronald G. Chesemore