SUBJECT:

Exchange of Inspectional Information on Medical Device GMP

Notes:

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

Tel. No. 301-594-4692
FAX No. 301-594-4610

This EOL is in effect indefinitely.

Office of Standards and Regulations no longer exists. Director, Office of Compliance, HFZ-300 (Currently: Lillian Gill) 2098 Gaither Road Rockville, MD 20850

EXCHANGE OF LETTERS

Elizabeth D. Jacobson
Director, Office of Standards and Regulations
Center for Devices and Radiological Health
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20785

Dear Dr. Jacobson:

This letter reflects the establishment of a mechanism for facilitating the mutual exchange of medical device Good Manufacturing Practice (GMP) inspectional information, between the Therapeutic Devices Branch, Therapeutic Goods Administration (TGA), Department of Health, Housing and Community Service, Australia, and the Center for Radiological Health (CDRH), U.S. Food and Drug Administration (FDA), U.S.A.

The TGA endorses the mutual exchange of medical device GMP inspectional information between our two nations. In a spirit of co-operation, and on behalf of the TGA, I agree herewith as follows:

1. Upon request from the FDA, the TGA will furnish copies of medical device GMP establishment inspection reports of Australian manufacturers that export to USA. The TGA will also provide, upon request, information obtained under TGA's medical device problem reporting scheme.

2. Information shall be provided to the extent that Australian law permits and on the understanding that it will be treated as confidential for intra-agency use only. Such information 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.

3. Joint inspections of medical device manufacturers may be conducted in Australia and the United States, provided the manufacturers so consent. This will allow opportunities for comparing inspection and reporting techniques, for exchanging inspection experience and for developing common administrative practices that would enable the mutual recognition of inspectional findings of our respective auditors and investigators.

4. When the TGA discovers during the course of its inspectional activities, 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 finding to the FDA.

Notes:

5. At appropriate intervals, and by mutual agreement, the TGA will arrange for meetings between its auditors, technical experts and management and those of the FDA for the purpose of reviewing the progress made through implementation of this information exchange.

6. Liaison officers for the purpose of coordinating these provisions are as follows:

A. For FDA:
Director, Office of Standards and Regulations (HFZ-80)
Center for Devices and Radiological Health
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
U.S.A.
Telephone (301) 443-3403
FAX: (301) 443-1627

A.
Director, Office of Compliance and Surveillance (HFZ-300)
(Currently: Lillian Gill)
2098 Gaither Rd., Rockville, MD 20850

Telephone:
(301) 594-4692
Fax
(301) 594-4610

B. For TGA:

Director, Therapeutic Devices Branch
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606
Telephone: 06 239-8700
Fax: 06 239-8687

I am confident that the implementation of these provisions on a reciprocal basis will provide a sound basis upon which we may plan, program and build, in partnership, better health protection for our two nations.

Yours sincerely,

Dr. Derrick Beech
Director
Therapeutic Devices Branch

7 February 1993

Notes:

February 17, 1993

Dr. Derrick Beech
Director, Therapeutic Devices Branch
Therapeutic Goods Administration
P.O. Box 100
Woden, ACT 2606
Australia

Dear Dr. Beech:

The U.S. Food and Drug Administration (FDA) is pleased to cooperate with your government in facilitating the rapid exchange of documents and information, including Good Manufacturing Practice (GMP) inspectional information pertaining to medical devices.

Upon request from the Therapeutic Goods Administration (TGA), Australia, the Center for Devices and Radiological Health, FDA will furnish the purged (proprietary information removed) copies of medical device GMP Establishment Inspection Reports (EIRs) of the U.S. manufacturers that export to Australia, pursuant to Title 21, Code of Federal Regulations Section 20.89. This regulation governs FDA's communications with foreign governments under the Freedom of Information Act. A copy is enclosed for your information.

Further, FDA will be receptive to TGA's request to observe inspections of medical device manufacturers in the United States, when consent is provided by the manufacturers. This will provide opportunities for the comparison of inspection and reporting techniques.

The FDA will also provide, upon request, Device Experience Network reports, e.g. reports required of manufacturers on device failures/malfunction by the Medical Device Reporting Regulations.

When FDA discovers, during the course of inspection activities, or through other means, particular circumstances whereby a medical device presents an imminent and serious danger to the public, FDA will communicate its findings to the TGA in accordance with Title 21, Code of Federal Regulations, Section 20.89.

To help ensure that this information exchange initiative works well and meets our needs, we feel that it is important that, at appropriate intervals, and by mutual concurrence, a discussion or meeting take place to assess the activities outlined in this letter.

Notes:

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

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301-594-4692
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The FDA contact for these activities is as follows:

Philip B. White
Director, Office of Standards and Regulations (HFZ-80)
Center for Devices and Radiological Health
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This information exchange initiative should lay the ground work for the development of common administrative practices that could lead to the mutual recognition of inspectional findings of our respective investigators.

FDA will be glad to work with your government in exploring means which will lead to further cooperation, such as a Memorandum of Understanding in the medical device area. We look forward to receiving your response.

Sincerely yours,

Elizabeth D. Jacobson, Ph.D.
Acting Director
Center for Devices and Radiological Health

Director, Center for Devices and Radiological Health is currently: Bruce Burlington, M.D.