法規名稱：AN EXCHANGE OF LETTERS REGARDING THE MUTUAL EXCHANGE OF INFORMATION ON MEDICAL DEVICES, INCLUDING QUALITY SYSTEMS REQUIREMENTS IN SPECTION INFORMATION (AD.1998.01.09)

簽訂日期：民國 87 年 01 月 09 日

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January 9, 1998

Mr. Stephen S. F. Chen
Representative
Taipei Economic and Cultural
Representative Office in the U.S.
4201 Wisconsin Avenue, N.W.
Washington, DC 20016-2137

Dear Representative Chen:

I have the honor to propose an exchange of letters regarding the mutual exchange of information on medical devices, including Quality Systems requirements inspectional information. This exchange of letters will further the cooperation between public health professionals from the United States of America and Taiwan.

The Taiwan Relations Act (Public Law 96-8, April 19, 1979) authorizes the continuation of commercial, cultural and other relations between the people of the United States and the people of Taiwan. Such relations are conducted by or through the American Institute in Taiwan (AIT), a non-profit corporation, incorporated under the laws of the District of Columbia. The Taipei Economic and Cultural Representative Office (TECRO), formerly the Coordination Council for North American Affairs (CCNAA), is the instrumentality which has been established to provide assurances and take actions on behalf of the people on Taiwan. For the purposes of this exchange of letters, AIT will work in association with the U.S. Food and Drug Administration (FDA) in Rockville, Maryland, in administering this program. TECRO will perform a similar function in affiliation with the Department of Health (D-

OH) in Taipei.

Upon request from TECRO, AIT intends to furnish purged copies (i.e., the non-public information will be removed) of medical device Establishment Inspection Reports (EIR's) of the United States manufacturers that export to Taiwan.

Further, it is the intention of AIT to notify TECRO prior to scheduling an inspection in Taiwan. Additionally, AIT intends to be receptive to requests by TECRO to observe FDA inspections of medical device manufacturers in Taiwan. TECRO may also make arrangements for AIT to observe DOH inspections of medical device manufacturers in Taiwan. It is intended that the mutual observation of each other's inspections will provide opportunities for the comparison of inspection and reporting techniques and to facilitate a mutual understanding of respective quality assurance programs. AIT also intends to provide, upon request, purged Device Experience Network reports (in the United States this is called the ”Medwatch Program”). The Medwatch Program is a vigilance system designed to provide reports from manufacturers on device failures/malfunctions required by the medical device reporting regulations. When AIT becomes aware of particular circumstances in which a medical device presents an imminent and serious danger to the public, AIT intends to communicate the findings to TECRO in accordance with Title 21, Code of Federal Regulations, Part 20.

AIT and TECRO will seek to coordinate and implement the activities of this exchange of letters with their designated representatives, the FDA and the DOH. Each side shall designate a program coordinator to be responsible under its auspices for overall coordination of the activities under this exchange of letters. AIT and TECRO program coordinators will meet at times and places of their choosing to review the operation of the information exchange.

If the activities and the terms set forth in this letter are acceptable to TECRO, this letter together with your reply shall constitute an exchange of letters between AIT and TECRO and shall be implemented upon your reply.

Sincerely,
[Signed]
Richard C. Bush
Chairman of the Board
and Managing Director

January 9, 1998
Dr. Richard C. Bush
Chairman of the Board
and Managing Director
American Institute in Taiwan
1700 North Moore Street, 17th Floor
Arlington, VA 22209

Dear Dr. Bush:
I have the honor to acknowledge receipt of your letter dated January 9, 1998 which reads as follows:

" I have the honor to propose an exchange of letters regarding the mutual exchange of information on medical devices, including Quality Systems requirements inspectional information. This exchange of letters will further the cooperation between public health professionals from the United States of America and Taiwan.

The Taiwan Relations Act (Public Law 96-8, April 19, 1979) authorizes the continuation of commercial, cultural and other relations between the people of the United States and the people of Taiwan. Such relations are conducted by or through the American Institute in Taiwan (AIT), a non-profit corporation, incorporat-

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Upon request from TECRO, AIT intends to furnish purged copies (i.e., the non-public information will be removed) of medical device Establishment Inspection Reports (EIR's) of the United States manufacturers that export to Taiwan.

Further, it is the intention of AIT to notify TECRO prior to scheduling an inspection in Taiwan. Additionally, AIT intends to be receptive to requests by TECRO to observe FDA inspections of medical device manufacturers in Taiwan. TECRO may also make arrangements for AIT to observe DOH inspections of medical device manufacturers in Taiwan. It is intended that the mutual observation of each other's inspections will provide opportunities for the comparison of inspection and reporting techniques and to facilitate a mutual understanding of respective quality assurance programs. AIT also intends to provide, upon request, purged Device Experience Network reports (in the United States this is called the ”Medwatch Program”). The Medwatch Program is a vigilance system designed to provide reports from manufacturers on device failures/malfunctions required by the medical device reporting regulations. When AIT becomes aware of particular circumstances in which a medical device presents an imminent and serious danger to the public, AIT intends to communicate the findings to TECRO in accordance with Title 21, Code of Federal Regulations, Part 20.

AIT and TECRO will seek to coordinate and implement the activities of this exchange of letters with their designated representatives, the FDA and the DOH. Each side shall designate a program coordinator to be responsible under its auspices for overall coordination of the activities under this exchange of letters. AIT and TECRO program coordinators will meet at times and places of their choosing to review the operation of the information exchange.

If the activities and the terms set forth in this letter are acceptable to TECRO, this letter together with your reply shall constitute an exchange of letters between AIT and TECRO and shall be implemented upon your reply."

In reply I have the honor to accept, on behalf of TECRO, the foregoing understanding and to confirm that the aforesaid letter and this reply shall constitute an exchange of letters between AIT and TECRO, effective on today's date.

Sincerely,
[Signed]
Stephen S. F. Chen
Representative