U.S. Department of Commerce
International Trade Administration
Manufacturing and Services
Office of Health & Consumer Goods
U.S. – China JCCT Pharmaceuticals and Medical Devices Subgroup
Summary of Medical Devices Task Force Meeting
April 14-15, 2009

I. Background

On April 14 -15, 2009, the U.S Department of Commerce hosted the 13 year anniversary meeting of the U.S.-China Joint Commission on Commerce and Trade (JCCT) Pharmaceuticals and Medical Devices Subgroup meeting (Subgroup). The JCCT activities kicked off on April 13 with a day-long seminar hosted by AdvaMed on adverse event reporting (AER) and risk management, which included a presentation by Inspector General Wang Laming on China's adoption of a recent rule on AER.

On April 14, 2009, the Subgroup meeting commenced with opening remarks by DAS Ira Kasoff, Counselor Chang Wenzou, and Jeffrey Gren followed by a presentation by SFDA on China's new health care reform plan. The meeting concluded with both the U.S. and China agreeing to a substantial 2009-2010 Work Plan, which includes activities that will facilitate market access for U.S. medical device and pharmaceutical companies in China.

The following is a summary of the Medical Devices Task Force meeting which was Co-Chaired by Mr. Vince H. Suneja of the Office of Health and Consumer Goods (OHCG) and Mr. Wang Laming of the SFDA's Department of Medical Devices.

II. Medical Device Task Force Agenda Items

- Product Registration
- Adverse Event Reporting
- US FDA Presentation on the Importation and Exportation of Medical Devices
- Unique Device Identifiers
- Wrap up and Approval of Work Plan

III. Medical Devices Task Force Meeting Summary

A. Product Registration

1. USFDA Presentation

John Stigi of the USFDA provided an overview of the FDA's structure and the Center for Devices and Radiological Health's (CDHR) role in product registration. Mr. Stigi's presentation focused on the 510K premarket notification system which accounts for the majority of devices marketed in the U.S. Mr. Stigi also provided

a flow-chart that provides guidance to both industry and regulators on the process utilized to determine whether a change to a device constitutes a "significant" change that would trigger notification to FDA (e.g., 510K premarket notification).

2. U.S. Proposal on Partial Changes

The U.S. expressed concerns with China's current requirement of re-registration of medical devices every four years, irrespective of any change that has been made to the device since initial approval. The U.S. proposed that SFDA consider adopting a system that would require reporting of insignificant changes in the company's quality management report and ultimately eliminating re-registration in favor of reviewing significant changes only.

The SFDA appreciated the proposal and remarked that China is moving towards the adoption of a Quality Management System (QMS) approach. In addition, SFDA noted that Decree 16 – which deals with medical device registration – will be coming out for public comment and encouraged industry to compile their comments and submit them to the SFDA.

Both U.S. and SFDA agreed that the next Medical Devices Task Force meeting should include a discussion on "partial changes," including what constitutes a significant change and related reporting/regulatory review requirements.

B. Adverse Event Reporting Rules

U.S. proposed that China's adverse event reporting rule requiring reporting of events that take place outside of China within 15 days is considerably less than GHTF guidance documents and does not provide sufficient time for translation and analysis by industry.

In addition, U.S. requested confirmation that proprietary information would not be made public, and that given the short time requirement the SFDA would not take action until the company had enough time to adequately analyze the adverse event. Further, U.S. requested clarity on whether the "re-evaluation" process mentioned in China's new adverse event rule would require full re-registration.

SFDA expressed confidence that their reporting timelines were sufficiently long enough for companies to report adverse events. They assured the meeting participants that they would not take any action on adverse events until they understand the full scope of the problem. They also pointed out that companies are free to submit subsequent reports within 20 days. Lastly, SFDA officials made a point of mentioning that there would be no need for the SFDA "step in" and "take

action" so long as companies exhibit a robust recall system for dealing with adverse events.

C. USFDA Presentation on the Import and Export of Medical Devices

Mr. Stigi of the USFDA gave a presentation on U.S. procedures for the import and export of medical devices. The SFDA delegation was particularly interested in the U.S. regulations with regards to medical devices that are manufactured in the U.S. solely for export. China is planning to revise its regulations in the future with more focus on the supervision of products for export.

D. Unique Device Identifiers (UDI)

1. USFDA Presentation

Jay Crowley of the USFDA gave a brief presentation on developments related to the implementation of UDI for medical devices in the U.S. Mr. Crowley explained that U.S. has been working on the implementation of a UDI system for the past 6 years but was mandated by Congress in 2007 to implement a UDI system. Mr. Crowley emphasized that global harmonization is key to successful implementation of a UDI system. In addition, Mr. Crowley noted that in February 2009, the USFDA held a public workshop on UDI implementation and expects to have a proposal published by the end of this year. Mr. Crowley also mentioned that the GHTF will likely come out with its own guidance documents for UDI implementation sometime during 2009.

2. Industry Presentation on Nomenclature

Janet Trunzo of AdvaMed gave a web demonstration of the Global Medical Device Nomenclature (http://www.gmdnagency.com/) system which has been under development for the past 15 years and contains 10,000 medical device terms.

The SFDA provided the group with an update on China's plans to implement a UDI system for medical devices. They expressed appreciation that the U.S. presentations covered both UDI and nomenclature as they are closely linked. The SFDA is concerned about the traceability of devices and has been paying close attention to GMDN, ISO 13485 and Quality Management Systems. Decrees 12 and 766 contain requirements for or references to UDI. GMPs for new medical devices are also being developed and will deal with this issue. Currently the

GMP for surgical devices requires a UDI. Most Chinese manufacturers of surgical devices use a laser to place the code on the device and that system in China needs to be standardized. The U.S. thanked the SFDA for the update and reiterated the importance and need for a harmonized system

E. 2009-2010 Work Plan and Wrap Up

U.S. and SFDA agreed to the following activities being included in the U.S. – China JCCT Pharmaceuticals and Medical Devices Subgroup 2009-2010 Work Plan as it relates to medical devices:

- UDI/Nomenclature event the week of June 22 in China
- Medical Device Task Force meeting in August-September (with partial change case study examples and an agenda item on combination products) in China
- Training session on technical review guidelines in China (TBD)
- SFDA site visits of medical device facilities in the U.S. (TBD)
- Annual JCCT meeting on April 12, 2010 in China

IV. Medical Devices Task Force Participants

China State Food and Drug Administration:

Mr. Wang Lanming, Acting Medical Devices Task Force Co-chair and Inspector-General, Department of Medical Devices
Mr. Jia Jianguo, Chief Inspector, Bureau of Inspection
Ms. Gao Jie, Division Director, Division of Registration I, Department of Medical Device
Ms. Du Huiqin, Division Director, Division of General Affairs, Department of Medical Device
Ms. Zhang Sumin, Division Director, Division of MDAE Monitoring & Re-evaluation, Center of Drug Reevaluation
Mr. Chang Yongheng, Deputy Director General, Center of Chinese Pharmaceutical International Exchange

U.S. Government:

Vince Suneja, U.S. Medical Devices Task Force Co-chair, and Director, Health Products and Technologies Team, Office of Health and Consumer Goods
Richard Paddock, International Trade Specialist, Office of Health and Consumer Goods
Lisa Rigoli, Market Access and Compliance Officer, Trade Facilitation Office, Beijing
Abby Pratt, International Trade Specialist, Office of Health and Consumer Goods
John Stigi, Center for Devices and Radiological health (CDRH), U.S. FDA
Chris Hickey, Country Director, People's Republic of China, U.S. FDA,
Jay Crowley, Senior Advisor for Patient Safety, U.S. FDA
Astrid Szeto, Associate Director for China, Office of International Programs, U.S. FDA
Diane Goldsberry, Center for Devices and Radiological Health (CDRH), U.S. FDA

Tanisha Adams, Center for Devices and Radiological Health (CDRH), U.S. FDA
Arlene Feldman, Center for Devices and Radiological Health (CDRH), U.S. FDA
Deborah Yoder, Center for Devices and Radiological Health (CDRH), U.S. FDA

U.S. Medical Devices Industry Representatives:

Carolyn Albertson, Abbott, Representing Advanced Medical Technology Association (AdvaMed)
Hans Beinke, Siemens Healthcare, Representing Medical Imaging & Technology Alliance (MITA)
Peter Coronado, Varian Medical Systems, Representing MITA
Edward Gibbs, International Association of Medical Equipment Remarketers and Suppliers (IAMERS)
Kathy Harris, DePuy Orthopaedics, Representing AdvaMed
John Jaeckle, GE Healthcare, Representing MITA
Linda Lin, Boston Scientific, Representing AdvaMed
Jim Southwick, Medtronic, Representing AdvaMed
Nancy Travis, Vice President for Global Strategy, AdvaMed
Janet Trunzo, Executive Vice President for Technology & Regulatory Affairs, AdvaMed
Stephen Vastagh, Director, International Programs, MITA
Scott Zhang, Philips Healthcare, Representing MITA