Summary of Joint Commission on Commerce and Trade (JCCT)
Medical Devices Task Force meeting
August 30, 2005

**Overview**

The U.S. – China Joint Commission on Commerce and Trade (JCCT) Medical Devices Task Force meeting was held in Beijing, China on August 30, 2005. The Special Counsel to the Secretary of Commerce made introductory remarks emphasizing the importance of the JCCT as a venue for increasing understanding between the United States and China. The medical device industry members of the delegation (industry) made presentations to China's State Food and Drug Administration (SFDA) on some of the issues that were of concern. Progress was made on a number of issues, especially those that had been discussed in previous Task Force meetings, and new issues were raised regarding SFDA's new Draft Regulations on Market Supervision of Medical Devices. The next JCCT Subgroup meeting, which will be the Subgroup's 10th anniversary, will be held in Beijing in March 2006.

**Opening Session**

The Medical Device Task Force was Co-chaired by Mr. Chang Yongheng, Assistant Counsel, SFDA Department of Medical Devices, and by Mr. Jay Biggs, Senior Analyst, Office of Health and Consumer Goods, U.S. Department of Commerce. U.S. and Chinese industry were well-represented on both sides. The Medical Device Task Force focused on 8 issues:

1) SFDA Adverse Event Reporting System
2) Draft Regulations on Market Supervision of Medical Devices
3) GHTF Guidelines and Chinese Product Standards
4) Duplication of Testing and Inspection Procedures
5) Re-registration requirements
6) Use of Quality Systems
7) Classification of IVD Products
8) Status of Regulations on Refurbished Medical Devices

Introductory Remarks

Special Counsel to the Secretary of Commerce Bruce Blakeman made introductory remarks noting that Secretary Gutierrez had interest in the results of the Task Force's meeting and praised the JCCT's role in increasing cooperation between the two countries. Mr. Blakeman stressed several issues: the protection of intellection property rights; the reduction of regulatory redundancy; and the streamlining of approval procedures.

SFDA Adverse Event Reporting (AER) System

The U.S. delegation began by emphasizing their support for the creation of an adverse event reporting system for medical devices. The delegation noted that there were several aspects of this new system that remain unclear, and made a series of recommendations to address this concerns:

- Clarify that SFDA and the national level AER center serve as the controlling authority for all investigations and re-evaluations of AERs
- Clarify that an authoritative action (recall) be taken only when adverse events constitute a clear and serious risk to public health
- Consider replacing the word "re-evaluation" with "investigation"
- Enable manufacturers to receive AERs concurrently with Chinese Government
- Eliminate re-registration unless there is significant change to the device. Rely on the Quality Systems audits and AER to assure and monitor quality and safety.
- Retain dialogue between China Government and manufacturers to ensure success of AER system

Industry's primary concern was that authority to initiate investigations and reports is divided between central SFDA and their provincial offices. FDA Director John Stigi stressed the importance of industry understanding what is expected of them and urged SFDA to specify the threshold for a "reportable event."

SFDA said that the U.S. concerns were covered in the latest draft, which was being reviewed by the SFDA Policy and Regulation Division. It would be released for comment before final approval. Responding to the individual recommendations, SFDA noted that the role of the provincial adverse event reporting centers is to undertake the initial investigation and provide this information to the national adverse event reporting center. The responsibility for making the final decision and taking action on adverse events will reside with the national center. SFDA said the final regulation would specify criteria for a recall, which would apply in the case of serious injury or death, or a serious threat to public health. They emphasized that all the relevant parties, including the manufacturer, would be involved. SFDA said they thought there was a misunderstanding of the "re-evaluation" concept and recommended having further discussions on this point in the future, saying some adjustment could be made if our understandings of the word were significantly different. SFDA agreed that the manufacturer must be made fully aware of adverse events and said the revised regulation provides for the manufacturer to be notified of an event concurrently with the relevant authority. SFDA said that the manufacturer bears ultimate responsibility for evaluating adverse events, and SFDA plays a supervisory role.

<u>Draft Regulations on Market Supervision of Medical Devices</u>

The U.S. delegation raised questions about a number of provisions in the draft regulations on Market Supervision of Medical Devices. Major concerns with the draft regulation included requirements that manufacturer be responsible for tracking devices all the way to the patient, and the requirement to track all implantable devices. Tracking devices all the way to the patient would be a tremendous burden on manufacturers due to a lack of access to information from distributors and hospitals regarding patients. Chinese medical device industry association (CAMDI) representatives participating in the Task Force meeting also expressed similar concerns. SFDA explained that they intended for manufacturers to only be responsible for tracking devices as far as the distributor or hospital, and indicated that this would be clarified in the final version of the regulation.

The U.S. delegation expressed concern over the requirement to track all implanted devices. Delegates explained that the U.S. FDA only requires require tracking for life-sustaining, life supporting devices implanted for more than 1 year and whose failure would have serious adverse health consequences. This excludes many orthopedic devices that are temporary implants, and many implants which are not high risk, such as steel rods and screws. SFDA responded that, under Chinese regulations, all implantable devices are classified as high risk, and therefore must be tracked. The U.S. delegation requested that SFDA consider either revising the regulation making all implantables high risk, or revising the Market Supervision regulation to specify only certain devices to be tracked. The U.S. FDA representative, John Stigi, explained that, 30 years ago, FDA also believed that all devices should be tracked. However, after analyzing failure rates, FDA concluded that that the added cost (which falls on the healthcare system, not the manufacturer) of tracking low-risk devices – such as bone screws – did not yield significant improvements in safety. SFDA said they would take our recommendation into consideration.

The U.S. delegation also raised concerns with a provision in the draft regulation for "spot testing." Delegation members asked for clarification on how spot testing would be conducted. Industry is concerned that, without proper safeguards, provincial authorities would apparently have the power to require and conduct "spot testing" in a manner that could lead to arbitrary restrictions on sales of medical devices. The delegation also reiterated industry's preference for the use of quality systems audits instead of product testing. SFDA indicated that this part of the regulation referred to the current practice of sampling and inspection of devices in the marketplace, which SFDA has been carrying out for five years. The government is in the process of developing implementing regulations on spot testing, which would be open for notice and comment. SFDA encouraged industry to provide comments as part of this process.

The delegation also raised concerns about the ban on selling medical devices used in clinical trials. The delegation noted that devices undergoing clinical investigations are costly and requiring that manufacturers provide these to patients for free would be prohibitively expensive for the manufacturer. Industry representatives also pointed out that, unlike drugs undergoing clinical investigations, most devices undergoing clinical trials are simply incremental improvements over previous models, so patients are virtually ensured of getting the benefits of the predicate device. In addition, patients and the health care payers receive an ongoing benefit from the long-term implanted devices even after completion of the trial. SFDA responded that, according to the supervisory regulation promulgated in July 2004, devices can only be sold after being registered, and since devices undergoing clinical trials are not registered, by definition they are ineligible for reimbursement. SFDA indicated interest in having further discussions to better define which devices require clinical trials, to reduce the number of products which have this requirement. In particular, they seemed interested in differentiating between a product that is completely new (which would require a clinical trial) and one that is an improvement of an existing product (which would not).

<u>GHTF Guidelines and Chinese Product Standards</u>

Following discussions during the April 2005 Task Force regarding SFDA's standards setting procedures (which tend to be inflexible in mandating compliance with all aspects of an internationally accepted standard), the U.S. delegation decided that it would be helpful to share with SFDA Medical Device Division staff information about the Global Harmonization Task Force (GHTF) guidance document on standards. Two delegation members, one of whom is a member of the GHTF Study Group responsible for standards, made presentations outlining GHTF guidance principles and making recommendations for their application to China's standards regime.

During the following discussion, the delegation emphasized the importance of adopting existing international standards wherever possible, as well as maintaining the voluntary character of these adopted international standards (as opposed to mandating mandatory national standards). They also emphasized the importance of active participation in standards development by all stakeholders. SFDA acknowledged the need to follow international standards, and indicated that they intended to increase the number of international standards that are adopted by 15 percent each year. They noted that notifications of proposed standards are routinely posted on the SFDA web site, and anyone can apply to get involved in the development of standards; in particular, foreign companies are permitted to provide comments. SFDA allows companies one year to accommodate to the new standard after it is introduced. SFDA said that mandatory standards were necessary for effective market supervision but pledged to promulgate more "recommended" standards. They noted that most mandatory standards respond to basic safety concerns.

Duplication of Testing and Inspection Procedures

SFDA noted that the AdvaMed paper submitted to the State Council in July, had been sent by Madam Wu Yi's office back to SFDA for comments. SFDA indicated that high level U.S. government follow up would be needed in order to resolve this issue. SFDA recommended sending another letter to the Legal Department of the State Council, as a follow-up to the letter that the U.S. Embassy sent in 2002. SFDA agreed that Wu Yi, as the official in charge of health, was a sensible recipient but also recommended reaching out to the official in charge of the Administration for Quality Supervision, Inspection and Quarantine (AQSIQ).

SFDA agreed that the problem has to be solved, noting that SFDA and AQSIQ had reached an oral agreement to eliminate the duplication but have not, in practice, solved the problem.

Re-Registration

During the August 2005 Task Force meeting, the U.S. delegation asked the SFDA to confirm that only products with major adverse events would require re-testing. SFDA responded that products with no major changes and no serious adverse events would not require re-testing. During the April 2005 Task Force meeting, SFDA indicated that there were six conditions under which a product could be exempted from type-testing during re-registration. At this meeting, SFDA said they were revising the regulation. Based on comments from industry that it was impossible for manufacturers to provide a report by a

Chinese-government-recognized inspection institution, or notified body indicating that a company is capable of testing its own devices. This was a topic that was discussed in depth during the April 2005 JCCT Subgroup meeting. SFDA indicated that they were dropping this as a requirement for exemption to type-testing during re-registration.

The U.S. delegation asked whether there could be a grace period during which products could stay on the market while they are undergoing re-registration, especially if there are new requirements. SFDA said this was covered in the revised regulation, which states that products can remain on the market once the application for re-registration has been filed. They warned, however, that many hospitals refuse to purchase products until the re-registration certificate has been granted. They also noted that the date of manufacture must predate the expiration of the registration; otherwise, the product cannot be sold. SFDA said the revised regulation is still under discussion between the Medical Device Department and the Policy and Regulation Department, but they expected that the new regulation will meet U.S. expectations.

Use of Quality Systems

The U.S. delegation provided a readout on the medical device Good Manufacturing Practice workshop. Industry lauded this as an important step in increasing SFDA use of Quality Systems, stressing that the Quality System is the foundation for ensuring quality. The U.S. delegation also noted that implementation of a Quality System eliminates the need to test individual products. The U.S. delegation asked for an update on SFDA's timetable for further use of Quality Systems. SFDA thanked Mr. Biggs and the U.S. delegation (many of whom had also participated in the GMP workshop) for their efforts. SFDA indicated that they intend to gradually require greater use of GMP, and hope to have all products manufactured under GMP in 10-12 years. They are attaching more importance to audits and are working to reduce product testing as much as possible. However, SFDA felt that local companies cannot implement the GMP system overnight, and therefore SFDA would need to continue testing products to ensure that manufacturers are properly maintaining their Quality Systems. Once manufacturers have successfully implemented Quality Systems, SFDA would revise its management methods. SFDA officials expressed interest in participating in additional educational events to broaden their understanding of the definition of GMP and its applicability to the Chinese market.

Classification of IVD Products

The delegation, asked for an update of the status of SFDA's regulations on In Vitro Diagnostics (IVD) products. Following the discussion on this topic during the April Subgroup meeting, AdvaMed has submitted a paper to the SFDA Commissioner making a recommendation that IVD products be regulated as medical devices using a risk-based classification system. During the Task Force meeting, delegation members noted that many IVD registration applications were still awaiting approval, causing great difficulty for manufacturers. SFDA responded that while final regulations had not yet been promulgated, SFDA was considering regulating most IVD products as devices, with the exception of biologics such as HIV tests, which would remain under the jurisdiction of the SFDA Pharmaceutical Department. They said that, until the decision is finalized, IVD products were still subject to the 2002 notice which set out which would be

regulated as devices and which as drugs. Some applications were submitted as drugs and some as devices due to lack of clarity in the original notice. These applications were not likely to be approved until the new decision was finalized.

SFDA indicated that they were researching how to effectively implement the new system, and accepted a U.S. delegation proposal to hold an IVD Roundtable on this subject. SFDA suggested holding this Roundtable within the next couple of months in order for industry's input to have an effect on the upcoming regulations. They requested that the U.S. send experts to introduce the legal framework for dealing with this issue in the U.S., which would be beneficial to the technical development of the regulations, such as which products need clinical trials.

Status of Regulations on Refurbished Medical Devices

The U.S. delegation asked for an update on when the draft regulations on remanufactured equipment would be finalized. SFDA responded that, based on negative feedback they had received from domestic industry and from society in general, they had decided not to move forward with these regulations. Chinese industry association representatives shared some of their concerns with the U.S. delegation.

**Accomplishments**

This Task Force meeting was very successful in advancing the U.S. Department of Commerce's healthcare agenda. Accomplishments included:

- Confirming that SFDA will post revised Adverse Event Reporting regulations, on the SFDA website by July 15, 2006. These revised regulations will specify that provincial adverse event reporting centers will be limited to undertaking initial investigation and provide information to the national adverse event reporting center. National adverse event reporting centers will be responsible for making the final decision. These new draft regulations will also specify that a recall would only be undertaken n the case of serious injury or death, or a serious threat to public health; and require the manufacturer to be notified of an event concurrently with the relevant authority.

- Reaching agreement with SFDA and the Chinese medical device industry association on the need to have end users play a role in tracking of implantable medical devices.

- Learning that SFDA will accept U.S. industry input on draft regulations on "spot checking" of medical devices under the Market Supervision of Medical Devices draft regulations.

- Learning of SFDA plans to increase the number of international standards that are adopted by 15 percent each year and aims to create more voluntary standards.

- Confirmation that products can stay on the market during re-registration, as long as the application for re-registration has been filed on-time and the date of

manufacture predates the expiration of the original registration, and that manufacturers will no longer have to provide certification of self testing, in order to avoid type testing during the re-registration process.

- Confirmation that SFDA is considering treating most In Vitro Diagnostics products as medical devices, and reaching agreement to hold an IVD Roundtable to discuss how these regulations will be implemented.

- Getting a sense of SFDA's timeline for introduction of Quality Systems.

- Agreed to hold the next JCCT Medical Devices and Pharmaceuticals Subgroup in Beijing in late March 2006.