Report on April 8-9, 2008 U.S. - China JCCT Medical Device Task Force Meeting

The Joint Commission on Commerce and Trade (JCCT) Medical Device and Pharmaceutical Subgroup met April 8-9, 2008 in Guilin, China, with regulatory training on April10-11. SFDA Medical Device Department Director General Wang Baoting led the Chinese delegation but left early, missing half a day of negotiations and all the training. Ms. Gao Jie, Director of the SFDA Medical Device Product Registration Division, took over in his stead.

There were five main achievements of the JCCT:

1) SFDA agreed to lift the requirement for product testing for re-registrations with no changes or minor changes. This will take effect after the revised medical device regulation (State Council Order 276) is promulgated, hopefully by the end of the year.
2) SFDA confirmed that name changes, such as that following a merger, would not require a full re-registration, just a name-change submission and declaration that there was no change to the Quality System.
3) SFDA agreed to eliminate the proposed restrictions on ports of entry for imported medical devices. However, they maintain the right to conduct sample inspections of imported shipments, saying they are necessary to ensure safety and citing the example of the pacemakers that were refused entry in 2007.
4) SFDA agreed to extend the product registration validity from four years to five years for in vitro diagnostic products and is willing to discuss retaining the original license number after re-registration, to simplify labeling, and to considering amending classification and nomenclature requirements.
5) SFDA committed to work hard to reduce the product approval backlog and said they have already transferred 20 reviewers from provincial FDA offices and were in the process of hiring 15 more reviewers from universities. They agreed that proper training and supervision was important. SFDA hopes to clear the backlog by the end of the year.
6) SFDA pledged to work to streamline and improve the product testing process and noted there would be a meeting at the end of April focused on better organizing the various test centers.

There were also several areas of ongoing concern:

1) SFDA continues to insist on type-testing for registration and for re-registrations involving major changes. SFDA essentially said that the local companies could not be trusted and that type-testing was needed to ensure safety, even if the quality system has been inspected and approved. One option to consider would be to advocate for a transitional process to exempt firms with approved quality systems from type-testing, but we still have a significant hurdle to overcome related to SFDA's perception of the unreliability of the local firms and SFDA's unwillingness to grant differential treatment to foreign firms.
2) SFDA refuses to lift its requirement for registration in the country of export, but they did open the door to having a discussion on substituting approval in one of the GHTF

founding members. SFDA noted that US FDA is asking SFDA to approve Chinese-made products destined for export.

3) SFDA is organizing a board of medical device experts to give advice but is excluding foreign companies from the board.

4) SFDA continued to affirm that use of national standards for product registration is required by Chinese law but said that they would consider company-developed standards and international standards if the company could prove that they were the best way to assess the product's safety and efficacy.

5) BSE discussions were inconclusive, and SFDA still needs more technical information from us to lift its ban on medical devices containing bovine material from BSE countries.

6) There was a different tone to this meeting, which delegates judged to be stemming from the fact that SFDA has its own dialogue with the US FDA under the Memorandum of Agreement signed last year. FDA's absence at the JCCT meeting was noted several times, and in her closing remarks Ms. Gao said it was unfortunate that FDA was not on hand to answer Chinese industry questions. On a few occasions, SFDA referred to other discussion with FDA and was unwilling to commit to future JCCT meetings, wanting to wait to see what other meetings would be scheduled with US FDA.

Follow-up items include: 1) A thank-you letter to SFDA confirming the gains and citing areas for future work (AdvaMed will draft); 2) a letter to the State Council urging faster progress on quality systems (Medtronic will draft); and 3) technical guidelines on BSE risk management to SFDA (BSE Subgroup will draft). AdvaMed will circulate the JCCT summary and the draft documents (except for #3) to the China Regulatory Working Group for review and/or approval.