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CFDA ISSUES PROPOSED REGULATIONS ON MEDICAL DEVICES

On March 20, 2013, the China Food and Drug Administration (CFDA) released for public comment two proposed regulations on medical devices.[1] The first regulation, *Special Review and Approval Process for Innovative Medical Devices (Interim) (draft)*, provides for special review and approval for qualified devices for which the applicant holds intellectual property rights. The second, *Regulation for Simplification of Application Materials Required for Medical Device License Re-registration (Interim) (draft)*, simplifies the application materials required in license re-registration process. The comment period for the proposed regulations ended on March 31, 2013. Medical devices companies doing business in China should closely monitor the development of the proposed regulations in order to be ready for the changes when the regulations are finalized.

SPECIAL APPROVAL PROCESS FOR INNOVATIVE MEDICAL DEVICES

As the preamble and Article 1 of the measure state, the proposed special review and approval process for innovative medical devices is an effort by CFDA to help meet the Chinese government's directive to increase innovation in the medical device industry.[2]

Who Qualifies?

To qualify for the special review and approval process, an applicant must meet the following four requirements:

- The applicant owns the intellectual property to the product core technology, and the ownership is clear. "The applicant owns the intellectual property" means that the applicant either (i) through the technology innovative activities that itself leads, lawfully owns the title to the invention patent in China, or (ii) lawfully obtains, through transfer, the ownership or use right to the invention patent in China.
- The primary principles of function or mechanism of action of the medical device must have been the first of its kind in China and offer a fundamental improvement in safety or performance over same type of products. The device must be in a leading position globally from a technological perspective, and have significant clinical value.
- The applicant must have finished early stage R&D and have developed a basic prototype. The R&D process must be genuine and well-controlled, and the research data complete and traceable.

[1] CFDA Proposed Measures are available at http://www.sda.gov.cn/WS01/CL0779/79239.html.

[2] In the Twelfth Five-Year (2011-2015) Plan, the government included an initiative to increase the development of medical device made in China. In the Special Five-Year Plan for the Medical Device and Equipment Industry, the Ministry of Science and Technology detailed technological benchmarks such as the development of 200 core patents and the creation of 50 to 80 new medical device products.

- The applicant must be a legal entity in China (can be a wholly foreign owned enterprise, joint venture, or Chinese state or private owned enterprise), manufactures the device in China, and holds the appropriate medical device manufacturing license.

How is the Proposed Special Review and Approval Process Different?

The special review and approval procedure for qualified medical devices differs from the normal approval process in three main ways. First, the review and approval process will be managed by a special office within CFDA. Second, priority review will be given at every stage of the review and approval process and at every level of the agency. Third, there will be prompt communication with and guidance to the applicant through multiple channels, ranging from the appointment of a special government liaison for the applicant to the establishment of formal communication channels.

REGULATION FOR SIMPLIFICATION OF APPLICATION MATERIALS REQUIRED FOR MEDICAL DEVICE LICENSE RE-REGISTRATION

The proposed regulation is designed to lessen the burden of the medical device license re-registration process. Under Article 14 of the *Regulations for the Supervision and Administration of Medical Devices* and Article 4 of the *Measures for Medical Devices Registration*, a registration certificate for a medical device is only valid for four years, and requires renewal prior to expiration. Under Article 34 of the *Measures for Medical Devices Registration*, if any of the following changes — model specification, manufacturing address, product standards, functional structure or components, or indications for use — the device manufacturer must apply for re-registration within 30 days.

Under the proposed regulation, the device manufacturer is allowed to provide fewer application documents if there has been no material change in safety or efficacy. If there have been changes to the model specification, manufacturing site address, product standards, functional structure or components, or indications for use, the applicant needs only provide documents related to that change, and no longer needs to re-submit the operation manual, product standards, and test reports.

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