International Devices & Diagnostics Monitor

China FDA Allows Self-Inspections For Device Distributors

By Joya Patel

June 27, 2016 - China FDA is requiring distributors of Class II and III devices to conduct self-inspections and report on their business activities.

Manufacturers with distribution hubs in China will need to conduct audits of their distributors to ensure they are compliant.

The move is yet another measure the agency is taking to consolidate the market, because it believes the reports will expose non-compliant manufacturers.

“There could be a significant amount of disruption at the end of this go-to-market process,” Helen Chen, managing director and partner at L.E.K. Consulting in Shanghai, told *IDDM.* CFDA will review self-inspection reports on three types of distributors: foreign device distributors, those with noted poor management and cold supply chains.

According to Katherine Wang, partner at Ropes & Gray LLP, subsidiary distributors acting as domestic agents for imported medical devices are key targets of the current enforcement campaign.

As second- and third-level distributors are common in China, a given manufacturer may have a high portion of their sales come from small distributors several steps away from their audited distribution partner, adds Chen.

Thus, manufacturers at highest risk are those with only a sole national distributor that is noncompliant with good supplier guidelines and invested in the labeling, warehousing and record keeping requirements.

Manufacturers with first-level distributors are most likely to control their product distribution and will likely be less impacted, she said.

Chen recommends that manufacturers of Class II and III devices review their own distributor audit records against the listed criteria, and reconfirm qualifications with their distribution partners.

Manufacturers that already track product sellouts should review the list of their lower level distributors and sales exposure.

Distributors will need to check their distribution records going back to June 1, 2014 and report on Class II and III devices which:

●● Lack CFDA registration certificates;
●● Do not meet mandatory standards or technical requirements of their registrations;
●● Lack qualified and valid documentation and licensure;
●● Do not have an established stock inspection records policy;
●● Have insufficient labels and/or indications for use that do not comply with current CFDA regulations; and
●● Show any instances where instructions

and label indications for transport and storage of a device were not followed.

If distributors refuse to report, conceal self-inspection findings, or fail to take self-inspection seriously, they may face revocation of medical device distribution permits, Wang said.

Distributors are required to submit their reports to provincial officials by July 15, who will review the self-inspection reports and submit their findings to CFDA by Sept. 30.

Read CFDA's update here: www.fdanews.com/ 06-23-16-CFDAInspectionUpdate.pdf.

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