

Improving Quality and Compliance.

China Cracks the Whip Against Manufacturers Who Fail Quality Norms

As reports of allegedly substandard Chinese products make headlines in the western media, the emerging Asian giant has decided to tighten its regulation.

Five drug makers this year have seen their production licenses taken away and at least 125 others have been penalized. In the past month alone, a former department head at the State Food and Drug Administration was sentenced to death on bribery charges. The moves come as U.S. regulators ordered a recall of three more Chinese-made products deemed dangerous for humans, part of a lengthening list of recent U.S. government actions to ban, recall or restrict imported goods.

Read more about the government crack down [here](#).

FDA Increases Medical Device Registration Fees

The U.S. Food and Drug Administration (FDA) has announced in the Federal Register new registration fee amounts and payment procedures for medical devices for fiscal year (FY) 2009.

These changes, which were authorized by the Medical Device User Fee Amendments of 2007, will impact medical devices that are imported into the U.S.

View the full article with link to the FDA announcement [here](#).

What Preemption? Device Lawsuit Can Proceed

A federal judge in Texas has ruled that a lawsuit against a device maker can proceed, because preemption - as defined in a closely watched US Supreme Court ruling earlier this year - does not apply in this instance. And the decision suggests device makers may no longer be immune from some cases they have been unwilling to settle.

In the decision, US District Court Judge Barbara Lynn noted that "the relevant issue here is whether plaintiffs' strict liability and implied warranty claims impose duties on medical device manufacturers 'different from, or in addition to' those arising under the Medical Devices Amendments of 1976, triggering preemption." She went on to conclude that "plaintiffs' strict liability claims are predicated solely on violations of federal law," and as a result, preemption is not warranted.

Read the full article [here](#).

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