



The Honorable Edward J. Markey  
House of Representatives  
Washington, D.C. 20515-2107

JAN 10 2013

Dear Mr. Markey:

Thank you for your letter of August 15, 2012, cosigned by Senator Jeff Merkley, requesting information regarding the Food and Drug Administration's (FDA or the Agency) efforts to strengthen the Agency's medical device recalls and premarket notification (510(k)) databases to provide publicly available and readily searchable information regarding the safety of medical devices. We appreciate your continued interest and input concerning these important initiatives.

Section 605 of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Public Law 112-144, enacted July 9, 2012) directs FDA to use device recall information to "proactively identify strategies for mitigating health risks presented by defective or unsafe devices." FDA's efforts described below will help fulfill this mandate, and will be a priority for the Agency as we continue to improve the transparency and effectiveness of our system of medical device regulation.

We note that you have requested that FDA update its medical device recalls and 510(k) premarket notification databases to reflect certain information regarding devices that were subject to a recall because of a serious design flaw that negatively affects "safety or effectiveness." Product recalls are classified by FDA into three classes depending on the likelihood and seriousness of the adverse health consequences. *See 21 Code of Federal Regulations (CFR) 7.3(m)*. Design flaws that affect a device's effectiveness can result in adverse health consequences, which are included as "safety concerns." Therefore, we focus on safety in our responses below.

Your specific questions are stated in bold type below, followed by FDA's response.

- **Sponsors need better information about which devices could pose problems should they be named as predicates in a 510(k) submission. To provide better clarity for sponsors, is FDA willing to update its 510(k) database so that it clearly indicates devices that have been recalled for serious design flaws that could adversely affect safety or effectiveness? Please explain why or why not.**
  - **Will FDA update the database within 30 days after completing its review of a manufacturer's root-cause analysis which concludes**

**that a flaw triggering the recall was a serious one that could adversely affect safety or effectiveness? If not, why not?**

FDA agrees that it is important for sponsors to have information about medical devices that have been recalled for serious design flaws that could adversely affect safety, so that sponsors may either avoid using such devices as predicates or ensure that these design flaws are not replicated or that the risks from these flaws are adequately mitigated in the new device. FDA intends to modify its 510(k) premarket notification database to enable FDA to clearly indicate, in a timely manner, when a cleared device is the subject of a recall, where it is clear to FDA from the root-cause analysis or other information that the recall was due to a serious design flaw that could adversely affect safety. FDA also intends to provide a mechanism for linking from its 510(k) premarket notification database to additional information within its medical device recalls database.

- **Will FDA include in the database past recalls clearly marked for serious design flaws that could adversely affect safety or effectiveness, so device manufacturers and the public have comprehensive information about problematic predicates? If not, why not? If so, how many years back does FDA plan to update its database?**

FDA agrees that it is important for sponsors and the public to have comprehensive information about devices that have been recalled for serious design flaws that could adversely affect safety. To the extent resources permit, FDA intends to perform a review of recalled devices for which we have reliable information about the reason for the recall. Where this information indicates that the recall was due to a serious design flaw that could adversely affect safety, FDA intends to update the 510(k) premarket notification database to indicate devices that have been previously recalled.

- **If a company fails to show that their proposed 510(k) device either avoids or adequately mitigates the design flaw that caused a predicate's recall, is FDA willing to notify the sponsor in writing that this omission puts the device at risk of being deemed misbranded or adulterated? Please explain why or why not.**
  - **Will FDA include such notification in the 510(k) clearance letter issued to the sponsor? Please explain why or why not.**
  - **If so, will FDA include the 510(k) clearance letter in the 510(k) database within 30 days after the issuance of the letter, so that the public is aware that such devices may pose a health risk? Please explain why or why not.**

FDA agrees that there may be certain instances where it is appropriate for a manufacturer to use a device recalled for a serious design flaw as a predicate. As indicated in your letter, this could be the case, for example, if a manufacturer demonstrates to FDA that its new 510(k) device has addressed the design flaw of the

predicate or if the new device relies on an aspect of the predicate that is unrelated to the aspect that triggered the recall.

However, where, despite FDA's efforts to work with the sponsor to adequately address the design flaw, the new device repeats the serious design flaw that caused the predicate to be recalled and does not provide for adequate mitigation, if FDA determines the device to be substantially equivalent, then under the law the device would receive 510(k) clearance. This is so because, under section 513(f)(5) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA may not withhold clearance of a 510(k) because of the failure of a device to comply with requirements unrelated to substantial equivalence. FDA's substantial equivalence decision does not mean that FDA has made a determination that the device complies with other requirements of the FD&C Act and implementing regulations.

FDA will take all appropriate actions, within its legal authority, necessary to protect the public health from devices with serious design flaws that could adversely affect safety. Sponsors are responsible for complying with all applicable FDA statutory and regulatory requirements in order to lawfully market their devices. If a cleared device is determined by FDA to be misbranded or adulterated under sections 501 or 502 of the FD&C Act, it would be a prohibited act under section 301 of the FD&C Act for that device to be marketed or held for sale, despite FDA's determination of "substantial equivalence." Under such circumstances, FDA could take action within its legal authority to protect the public health, including removal of the misbranded or adulterated device from the market.

In appropriate instances, FDA intends to inform a sponsor, in a 510(k) clearance letter, that its device has been found substantially equivalent to a device that was recalled because of a serious design flaw that affects device safety and that, accordingly, its device may be misbranded or adulterated. FDA plans to subsequently provide a link to this letter in the Agency's 510(k) premarket notification database, as is standard practice for clearance letters.

- **Is FDA willing to revise its 510(k) premarket notification database to notify the public that a certain product repeats the same design flaw that caused a predicate's recall?**

FDA intends to update its 510(k) premarket notification database to indicate any marketed device that FDA has determined to be "substantially equivalent" under section 513(i) of the FD&C Act to a predicate device that was recalled for a serious design flaw that could adversely affect safety, where it is clear to FDA, based on the information received during the 510(k) premarket review, that the new device did not adequately address the predicate's design flaw.

- **To the extent feasible, can FDA develop a mechanism for identifying certain 510(k) entries to reflect instances where a device's clearance traces back to a predicate recalled for a serious design flaw adversely**

**impacting its safety, even if the original problematic device is not the immediate predicate?**

To the extent that resources permit, FDA intends to update its 510(k) premarket notification database so that the public will be able to easily navigate through predicate chains within the device type. This will enable the public to more easily trace a device's predicate history.

Thank you, again, for contacting us concerning this matter. If you have further questions, please let us know. The same letter has been sent to your cosigner.

Sincerely,



Michele Mital  
Acting Associate Commissioner  
for Legislation