



**TO:** CRDM Sales

**FROM:** [REDACTED]

**DATE:** November 17, 2009

Earlier today, [REDACTED] sent the attached message to CRDM employees worldwide related to an FDA warning letter. I wanted to provide you with additional talking points and a brief FAQ document for use in your conversations with customers.

We take the FDA letter seriously and have plans in place to address all of the areas of concern. Importantly, many of the corrective actions required to address the concerns in this letter are already under way. Therefore, we expect minimal disruption to business, if any at all.

Customer talking points (for your use. Do not print and distribute externally):

- Medtronic confirms it received a warning letter from the FDA related to an inspection of our Mounds View (CRDM) facility.
- We are committed to the highest quality and take this very seriously. CRDM is working with FDA to resolve the outstanding issues as quickly and thoroughly as possible.
- We began taking corrective actions in August following completion of the FDA inspection. The FDA wrote in the letter that our corrective action plan appears to be adequate to address the issues in the letter.
- We expect the remaining steps of our action plan to be fully in place shortly and will submit our follow up to the FDA in the coming weeks, then ask the FDA for a reinspection.
- We don't expect there to be a material impact on the business.
- There is no impact on physicians or patients, and no action is required of them.
- The entire organization is focused on satisfying the FDA's concerns in a timely manner, with a goal of ensuring there will be no delay in our new product launches as a result of this letter.

#### **Frequently Asked Questions**

##### **When do you expect to be cleared?**

We expect the remaining steps of our action plan to be fully in place shortly and will submit our follow up to the FDA in the coming weeks, then ask the FDA for a reinspection.

We are working closely with FDA, and have been since we received the related 483 letter in August. Many of our corrective actions are already underway, and the FDA has stated that our corrective action plan appears to adequately address the issues.

##### **What did the FDA warning letter cover?**

The FDA's observations fall into the following categories:

- Corrective and Preventive Action (CAPA) and field action timeliness;
- Review and documentation of field action recommendations;
- Supplier qualification and controls; and
- Medical Device Reporting (MDR) timeliness.

**What corrective actions are underway?**

CRDM has plans in place, and in fact is already addressing the observations mentioned in FDA's letter.

**Can you describe specifically what Medtronic is doing to address any of these four areas?**

We are implementing improved procedures and oversight to address each of the concerns raised by FDA.

**Do these observations impact your ability to pursue / launch new products?**

CRDM expects to complete its corrective actions within weeks and will request a follow-up inspection. It is our goal that through these efforts, there will be no impact any new product launches.

**Do we expect this warning letter to delay approval of AF Solutions products, currently under investigation?**

We are exploring this with FDA and wouldn't want to speculate. However, as we noted, we expect to have our action plan fully in place and will submit our follow up to the FDA in the coming weeks, then ask the FDA for a reinspection. It is our goal that through these efforts, there will be no impact on any new product launches.

**Are these observations related to Medtronic's recent warning letter related to its Neuromodulation and Diabetes businesses?**

No. Each Medtronic business or facility has a quality system that addresses the specifics of the business and products manufactured.

**Does Medtronic expect additional FDA enforcement as a result of these observations?**

We have provided the FDA with written responses that outline our clear commitments to addressing its observations after the inspection, and will reply to the warning letter within the specified time period. We remain committed to resolving the issues the FDA originally noted as quickly as possible and to the satisfaction of FDA. We cannot speak for the FDA or speculate about the future.

**When was the last time Medtronic CRDM received a Warning Letter?**

In 1998, CRDM's Rice Creek facility received a Warning letter.

**Do these observations relate to the Corporate Integrity Agreement Medtronic signed with the Department of Justice?**

No. The Corporate Integrity Agreement relates to different issues arising from a different business unit.

**Is there a major quality problem within the CRDM business?**

Quality is our top priority at all of our businesses. We continue to strive for higher quality throughout Medtronic by enhancing our systems, processes and accountability, and CRDM is no exception.

**What was the concern related to Fidelis?**

FDA observed that the October 2007 recommendation regarding patient alert programming was not reviewed, approved, and documented appropriately. There were no findings related to the validity of this programming recommendation or the current Fidelis patient management recommendations

**Medtronic has significantly more quality issues than competitors, what does this mean?**

We wouldn't agree that Medtronic has experienced significantly more issues, although Medtronic, like all medical device companies, has experienced challenges over the past two years.

**Do you think FDA is just sending out warning letters unnecessarily? If you are already addressing the issues, what was the point?**

The FDA has recently been quite open about the fact that it intends to take more aggressive action in response to perceived quality issues than it has previously. As such, it is true that, in the past, Medtronic may not have received a warning letter based on the FDA's level of satisfaction with our response to the earlier Form 483. However, this is an era of increased scrutiny and transparency, and Medtronic is committed to complying with all FDA requirements.

**Will there be further recall actions as a result of the warning letter?**

The FDA warning letter does not indicate the need for any further action on Kappa/Sigma or other issues.



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