DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0118]

Extreme Weather Effects on Medical Device Safety and Quality

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is studying the potential effects of extreme weather and natural disasters on medical device safety and quality. FDA is announcing at this time its request for comments on the topic of extreme weather effects on medical device safety and quality.

DATES: Submit either electronic or written comments by May 10, 2013.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jennifer Kelly, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3429, Silver Spring, MD 20993–0002, *Jennifer.Kelly@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Extreme Weather (EW) events and natural disasters can interfere with the manufacturing, shipping, storage, or use of marketed devices, which may lead to concerns with their safety or effectiveness. Examples of such events include hurricanes, floods, lightning storms, earthquakes, and fires.

FDA is holding a meeting of its Device Good Manufacturing Practice Advisory Committee on April 11, 2013, to discuss how to optimize the use of FDA's current regulatory framework to address risks and vulnerabilities to the manufacturing chain resulting from EW conditions. Future steps may be identified to help industry mitigate or better tolerate challenges to the manufacturing chain as a result of EW conditions. FDA is opening this docket to gather additional information to support FDA's efforts to minimize the impact of EW events on the safety, effectiveness, and availability of medical devices. FDA is requesting comments on three scenarios related to medical devices and EW. FDA will use this information to help industry anticipate and prepare for potential challenges from EW situations in the future.

Scenario A. Marketed Devices Already in Use for Patient Care

Medical devices in use for ongoing patient care may be damaged or prevented from functioning by EW conditions. In particular, those medical devices that are essential to ongoing patient safety, treatment, or comfort need to continue functioning even under less than optimal conditions such as electric power or network outages or lack of clean water. Examples include ventilators in hospitals, infusion pumps providing essential medicines at home, and dialysis machines in outpatient centers. The specific risks to patients and the best options for device optimization will depend on the type of product, the expected uses, and the locations of treatment.

Scenario B. New/Unused Devices, Components, or Accessories

Medical devices, components, or accessories may be damaged by EW conditions before use, while in storage, or during shipping. Examples include surgical gloves being held for shipment in a warehouse when it floods or weather interrupting transportation of temperature-sensitive devices.

Scenario C. Damage to Medical Device Manufacturing Sites

Medical device manufacturing facilities or equipment may be damaged during EW, limiting the number or quality of devices that can be produced until repairs are made. EW may also interrupt access to electric power, filtered water, or other necessary materials and utilities, thereby limiting production. Examples include a manufacturing plant damaged by fire, flooding in a storage warehouse, or power interruptions in clean rooms and other controlled environments during the manufacturing process.

FDA is seeking information particularly on the following questions; however, you may respond to any, all, or none of these questions, or you may submit comments on any topic relating to the purposes of this document, regardless of whether a topic is addressed by these questions:

1. Have you experienced any of the scenarios or any other effects of EW on the safety and effectiveness of medical devices?

2. How did you respond to extended periods of electrical or network outages or other events related to EW?

3. In past EW situations, how was communication handled between the manufacturer facility and patients/users about the safe use of products during EW events? How did you provide/receive information about device failures? Do you have any suggestions for complaint handling during these situations?

4. How should industry optimize the design, production, and use of medical devices during and after EW events?

5. How could products be monitored during transport and storage in light of potential interruptions and environmental extremes from EW events?

6. How can manufacturers best prevent or minimize temporary shortages of medical devices when EW may damage existing inventory or impact just-in-time production of critical components?

7. In what ways have EW events impacted your manufacturing site? What were the lessons learned during the recovery process as you returned to production? What changes were made as a result of the EW event?

8. Are there additional steps FDA can take to help industry anticipate, mitigate, or better tolerate the effects of EW?

9. Are there steps that standards development or other professional organizations can take to support industry to optimally prepare for EW events?

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Dated: February 14, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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