DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring, MD 20993-0002

Summary of the Device Good Manufacturing Practice Advisory Committee Meeting April 11, 2013

Introduction:

The Device Good Manufacturing Practice Advisory Committee met to discuss the potential effects of extreme weather and natural disasters on medical device manufacturing chain processes and marketed medical device safety and quality. The committee provided advice and recommendations to the FDA on the following issues: (1) successful practices that industry should consider to minimize risks of extreme weather affecting medical device safety and quality; and (2) how to optimize the use of FDA's current regulatory framework to address risks and vulnerabilities to the manufacturing chain resulting from extreme weather conditions.

Presentations:

Mr. Steve Silverman, Director of the Office of Compliance, Center for Devices and Radiological Health (CDRH), welcomed the advisory committee and provided opening remarks. Three FDA presentations followed: Extreme Weather Project; Quality System Regulation and Meeting Challenges of Extreme Weather; and the Compliance Program and Meeting Challenges of Extreme Weather.

Dr. Jennifer Kelly, Ph.D., FDA Commissioner's Fellow, provided the committee with the background of the extreme weather project and specific examples of extreme weather events and natural disasters. Dr. Kelly illustrated how these extreme events and resulting conditions may intersect with the medical device industry throughout the manufacturing chain leading to potential concerns about public safety. Ms. Jan Welch, MHS, MT(ASCP)SBB, FDA Deputy Director of Regulatory Affairs, presented specific parts of the Quality System regulation as

related to extreme weather challenges and vulnerabilities. CAPT Kimberly Lewandowski-Walker, FDA National Expert on medical devices, presented the Office of Regulatory Affairs' Compliance Program and how medical device inspectors approach extreme weather challenges to the medical device industry. The committee acknowledged the challenges to industry throughout the medical device manufacturing chain as a result of extreme weather conditions.

Dr. Philip Ferro, PH.D., MS, Director of Special Projects, Assistant Secretary of Preparedness and Response (ASPR), U.S. Department of Human Health and Services, discussed a health initiative project on building health resiliency technologies. This initiative is working on several components in parallel to build an integrated systems approach for health resiliency technologies. The plan to develop Durable Medical Equipment (DME) addresses communication infrastructure and tools, resiliency, and power. This effort integrates a multi-disciplinary and multi–agency team involving the ASPR, FDA, Federal Emergency Management Agency, and Biomedical Advanced Research and Development Authority.

Committee Deliberations/FDA Questions:

The committee members were unanimous in agreeing that the current Quality System regulation is sufficient and that a revision is not necessary. Committee members acknowledged that there is great opportunity for industry to design robustness into their device in the context of extreme weather challenges. The committee recommended that FDA continue to stay current with new technologies and incorporate new technology in its inspections. Additional recommendations to the FDA included categorizing and prioritizing regulatory oversight using a stratified risk-based approach considering critical medical devices, risk strategies, and sole manufacturers and suppliers as important factors. The committee recommended additional outreach to industry and stakeholders, moderate guidance updates addressing challenges of extreme weather, and developing course and training modules for stakeholders on successful practices in meeting challenges to extreme weather events. The committee also recommended that industry share its successful practices in the context of extreme weather events and experiences.

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