U.S. FOOD & DRUG ADMINISTRATION

APR 2 7 2018

The Honorable Greg Walden
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Walden:

Thank you for providing the Food and Drug Administration (FDA or the Agency) with the opportunity to testify at the October 24, 2017 hearing before the Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, entitled "Examining HHS' Public Health Preparedness for and Response to the 2017 Hurricane Season." This letter is a response for the record to questions posed by the committee.

If you have further questions, please let us know.

Sincerely,

John Martin
Principal Associate Commissioner
for Legislative Affairs

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Your questions have been restated in bold below, followed by our responses.

The Honorable Greg Walden

1. **Approximately how many of the pharmaceutical and medical device manufacturing facilities in Puerto Rico are still operating on generator power?**

   a. **How much longer can the facilities using generator power continue to rely on generator power?**

   As of October 24, 2017, we believe most, if not all, facilities are operating on generator power. While generators allowed many facilities to restart production, they are not a long-term solution.

   Updates on this status can be found on FDA's website.

   b. **Has the Food and Drug Administration (FDA) identified any preservation concerns or access issues associated with temperature-controlled pharmaceuticals, and if so what is it doing to address them?**

   FDA has undertaken swift and extensive efforts to prevent or limit the loss or shortage of multiple drugs critical to American patients due to challenges related to refrigeration, storage, and transportation. We have also been working closely with manufacturers to relocate products, and have been following critical infrastructure work done by our federal partners including: clearing roads to reach facilities; helping manufacturers procure fuel to keep generators running; and securing permissions to allow planes to land in Puerto Rico and fly critical products to the continental United States.

   c. **How many pharmaceutical and medical-device manufacturing facilities in Puerto Rico are fully functional?**

   As of October 24, 2017, we do not believe that many of the medical product facilities are fully functional. For pharmaceuticals, most are producing at anywhere from 20 percent to 70 percent of their normal capacity based on our own informal survey. One firm is producing at 100 percent of pre-hurricane output but they have dialed back certain other portions of the facility.

   Updates on this status can be found on FDA's website.

   d. **As the crisis in Puerto Rico has evolved have any new challenges arisen for pharmaceutical and medical device manufacturing facilities in Puerto Rico? If so, what steps is FDA taking to address those issues?**

   FDA is prioritizing its work with facilities that make critically important medical products to prevent or limit the impact of nationwide shortages. FDA is actively working with several companies who have requested assistance from FDA because their

manufacturing facilities in Puerto Rico were impacted by the hurricanes. And, we are working closely with the Federal Emergency Management Agency (FEMA) and other government partners as well. Our interventions have evolved as the nature of the risk has changed and our response progresses. Early on, we helped individual firms secure landing rights for planes to fly out finished products that were in some cases at risk of being destroyed by flooding warehouses. We are also working – with other government partners – to help facilities obtain fuel to keep generators running and, in certain cases, medical-grade gases that are used by some manufacturers.

A key challenge for the medical products facilities is obtaining access to the power grid. Many generators are old and not meant to function for months on end, and many facilities cannot return to full production on generator power alone.

As of October 24, 2017, we continue to be in contact with all firms that manufacture medical products we consider critical, where a falloff in production and an ensuing shortage could have public health implications. FDA is working to prevent and mitigate shortages of critically important medical products. We believe we have a good understanding of the potential risks and are taking steps to mitigate them. We are working with some companies to import medically necessary drugs from alternate manufacturing sites approved by a designated regulatory body, expediting review related to the import of medically necessary drugs from manufacturing sites that are not FDA approved, expediting review and approval of other dosage forms and generic versions, and approving production test methods to allow faster release of drug products to the market.

The Honorable Gus Bilirakis

1. **What challenges still exist for Florida and what are your post-storm recommendations?**

FDA recognizes that Hurricane Irma has led to hardships for many, and impacted drug and device manufacturers, as well as food and agriculture operations in Florida.
FDA has been working closely with drug and device manufacturers in all the affected areas to help prevent or mitigate a shortage, both before and after Hurricane Irma.
Crops and agriculture that were impacted by Hurricane Irma include citrus, avocados, tomatoes, sweet corn, bell peppers, sugarcane, cotton, and dairy from Florida. FDA has provided guidance to the industry regarding the safety evaluation of flood affected crops for human and animal consumption, as well as guidance for food manufacturers, warehouses, and transporters of food affected by floods or power outages.

Additionally, local intermittent blood shortages occurred in areas of Florida impacted by the storms. However, the AABB Interorganizational Task Force on Domestic Disasters and Acts of Terrorism, of which FDA is an active member, ensured areas impacted by the storms had sufficient levels of safe blood products on hand to meet local medical support requirements, primarily through coordination networks comprised of non-profit independent national and regional blood centers.

2. **What resources are available to communities like mine impacted by Irma?**

FDA recognizes that these hurricanes have presented unique challenges for those in the affected areas, and the Agency is committed to working with those who were impacted, as well as with our Federal and state partners, to help prevent or mitigate issues.

FDA has conducted assessments of the impact of Hurricane Irma on FDA-regulated firms and industries. For Hurricane Irma, FDA's Florida District Incident Management Team (IMT) conducted more than 2,380 post-storm assessments, and FDA staff remains available to answer any questions and provide assistance when appropriate.

The Honorable Frank Pallone, Jr.

1. **The widespread devastation in Puerto Rico caused by Hurricane Maria had a direct effect on pharmaceutical and medical device manufacturing facilities located on the island. Has FDA partnered with the suppliers of life-saving medicines to treat Puerto Rico's residents? What has the agency done to ensure facilities are well-equipped to ensure consistent production for residents in Puerto Rico and the rest of the nation?**

As an agency dedicated to promoting public health, and as fellow Americans, the staff at FDA are doing all they can to support the immediate needs of those affected by the destruction of these devastating storms. We are also working closely with our HHS colleagues and Federal partners to address the unique challenges facing Puerto Rico. FDA continues to work closely with medical product manufacturers to ensure availability of products that meet rigorous FDA standards for safety and efficacy. FDA is focusing on facilities that make critically important medical products to prevent or limit the impact of nationwide shortages.

Our interventions have evolved as the nature of the risk has changed and our response progresses. We are working closely with FEMA and other government partners. Early on we helped individual firms secure landing rights for planes to fly out finished products that were in some cases at risk of being destroyed by flooding warehouses, we have also worked to help facilities obtain fuel to keep generators running and, in certain cases, medical-grade gases that are used by some manufacturers, and to help local manufacturers who provide sterilization services to hospitals to get back online.

2. **During your testimony before this Committee on October 24 you stated that Puerto Rican pharmaceutical plants manufacturer 30 products that are considered "critical medicines" and that of those 30, 14 are sole-source products meaning that there are no alternative drug products available.**

    a. **Are all plants which manufacture the 30 critically-important products operating at full capacity today?**

As of October 24, 2017, we do not believe any of the medical product facilities are fully functional. Most are producing at anywhere from 20 percent to 70 percent of their normal capacity based on our own informal survey. One firm is producing at 100 percent of pre-hurricane output but they have dialed back certain other portions of the facility. We continue to monitor the situation and provide assistance as appropriate.

Updates on this status can be found on FDA's website.

b. Has the FDA evaluated how long each such plant can continue to operate under current conditions?

Our focus continues to be on plants that make critically important products and we are taking steps to try to mitigate the shortages that have occurred but are also looking at situations where we see the potential for a product to tip into shortage. We are typically looking out one-to-two months for what we think could potentially happen if full production does not resume.

c. What contingency plans has the FDA considered in the event that power and other capabilities are not restored by the first quarter of next year?

As of October 24, 2017, we continue to be in contact with all the firms that manufacture medical products we consider critical, where a falloff in production and an ensuing shortage could have public health implications. The FDA is working to prevent and mitigate shortages of critically important medical products. We believe we have a good understanding of the potential risks and are taking steps to mitigate them. We are working with some companies to import medically necessary drugs from alternate manufacturing sites approved by a designated regulatory body, expediting review related to the import of medically necessary drugs from manufacturing sites that are not FDA approved, expediting review and approval of other dosage forms and generic versions, and approving production test methods to allow faster release of drug products to the market.

3. On October 20 you released a statement that Puerto Rican manufacturers produce 50 types of medical devices that are critically important to patient care because they are life-sustaining and/or because they are produced by the only manufacturer of that device type. According to your statement, blood-related medical devices are of particular concern.

a. Are all plants which manufacture the 50 types of medical devices operating at full capacity today?

As of October 24, 2017, we do not believe that many of the medical product facilities are fully functional. We continue to monitor the situation and provide assistance as appropriate.

Updates on this status can be found on FDA's website.

b. Has FDA evaluated how long each plant can continue to operate under current conditions?

Our focus is on plants that make critically important products and we are taking steps to try to mitigate the shortages that have occurred but are also looking at situations where we see the potential for a product to tip into shortage. We are typically looking out one-to-two months for what we think could potentially happen if full production does not resume.

c. What contingency plans has the FDA considered in the event that power and other capabilities are not restored by the first quarter of next year?

As we continue to monitor at-risk devices, FDA will take other steps as appropriate to mitigate the potential for shortages, including considering, when necessary, importing a device from outside of the U.S. or allowing manufacturers to shift production to alternative sites.

4. What is the status of delivery of essential medical products to geographically remote areas such as Vieques, Culebra, St. Croix and St. Thomas?

FDA works with manufacturers to assess and address the overall, national supply of medical products. Regarding localized transportation and distribution of essential medical products, FDA defers to the HHS Assistant Secretary for Preparedness and Response.

The Honorable Jan Schakowsky

1. Following up, in the aftermath of disasters like these devastating hurricanes, government should provide relief and recovery workers with required health and safety protections and Personal Protective Equipment (PPEs) to ensure workers' health is not compromised during current and on-going clean-up and future rebuilding. Unfortunately we have heard that this is causing problems in Puerto Rico. We know that Puerto Ricans in both the private and public sector want to do the work needed to help rebuild their lives, homes, communities and their Commonwealth. Government workers are willing and eager to help address short-term needs – even when working as assigned by the Puerto Rico government is outside their long-standing responsibilities and expertise. Nonetheless workers simultaneously want to protect their own health and safety and avoid unnecessary health problems. The long-term medical problems flowing from the tragic events on September 11, 2001 and the resulting cleanup efforts at Ground Zero and on the Pile taught us the vital importance of providing appropriate health and safety equipment and training to workers in conditions that are dangerous or uncertain.

a. What is HHS, CDC, and other federal agencies going to ensure local Puerto Rico government employees have the necessary health and safety equipment to protect themselves during their ongoing relief and recovery work?

b. Have these issues been addressed in Puerto Rico?

c. Which federal agencies are responsible for providing needed PPEs to recovery workers?

FDA defers to the Centers for Disease Control and Prevention to answer these questions.

The Honorable Pete Olson

1. **After tackling 3 Hurricanes in the short period of time, what strains have you seen on your current resources? Also what additional resources to you need to help provide these communities that help that they need?**

FDA has spent about $3 million as of mid-October for hurricane response activities. We continue to use funding from our current budget to pay for staff time, travel, and supplies. We are working with the Administration to determine additional funding needs to help pay for repair of FDA facilities and equipment damaged by Hurricanes Harvey, Irma, and Maria.