U.S. FOOD & DRUG ADMINISTRATION

Ethylene Oxide Sterilization of Medical Devices Update

HICPAC

November 14, 2019

FDA/CDRH

Presentation Outline

- Framing
- Update on CDRH activities since May 2019
  - Shortages
  - Communications
  - Congressional
  - Stakeholder engagement
  - Innovation Challenge
  - Advisory Committee Meeting
    - ❑Key take-aways
    - ❑Recommendations
- Next Steps

Framing

Trigger: On February 15, 2019, the Illinois Environmental Protection Agency (EPA) issued a Seal Order to stop the Sterigenics facility in Willowbrook, Illinois, from sterilizing medical products and other products with ethylene oxide (EtO)

Closures and Potential Closures:

- Sterigenics-
  - Willowbrook IL- closed permanently- announced in Oct. 2019
  - Atlanta GA- closed temporarily- announced in Aug. 2019, timing of re-opening uncertain
- Becton Dickinson, in GA- closed temporarily- announced in Oct. 2019- reopened Nov 2019
- Medline Industries, in IL- future in jeopardy pending state legislation
- Viant- Grand Rapids MI- closing permanently

Shortages Assessment

- Monitor shortages mailbox
- Continue with identification and outreach to device manufacturers
- Continue information gathering via healthcare organizations, distributor groups, and trade organizations
  - To understand potential supply chain disruptions

Common theme- INCREASING concerns if additional facilities close or are forced to close

Communications

- 7/15/19 FDA Innovation Challenge: Preventing Medical Device Shortages by Ensuring Safe and Effective Sterilization in Manufacturing

- 10/25/19 FDA Commissioner's Statement on concerns with medical device availability due to certain sterilization facility closures

- 10/25/19 FDA Webpage updates
  - Main Page
  - Ethylene Oxide Sterilization Facility Updates

Congressional

- Held numerous briefings with states and federal stakeholders from May - November
- Provide information to help states understand the medical device EtO sterilization landscape
- Request states keep FDA/CDRH informed of their plans so we can take proactive measures to avert device shortages

Stakeholder Roles & FDA Engagement

- Sterilization experts role is educational
  - Objective of FDA engagement: To understand EtO reduction approaches and alternatives
- EPA's role is to regulate EtO emissions at state and national level
  - Objective of FDA engagement: To understand and inform EPA rulemaking and to maintain awareness of contract sterilizer site closures
- CDC's role is to understand the public health impact of EtO emissions from an epidemiological perspective
  - To understand and inform large scale cancer epi studies
  - To maintain awareness of state department of health cancer studies
  - To support communications of public health risk from environmental concerns to affected communities

Innovation Challenge

1. Identify new or alternative sterilization methods and technologies that are alternatives to those that use ethylene oxide.

2. Focuses on reducing ethylene oxide emissions.

November 2019 Advisory Committee Mtg: Key Take-Aways

- Patients would suffer from abrupt unavailability of devices sterilized using EtO
- The current EtO ecosystem cannot absorb additional facility shut downs
- Alternative methods have significant challenges due to material compatibility, scalability, packaging
- Moving completely away from EtO could take 10 years

November 2019 Advisory Committee Mtg: Recommendations

- Consider risk based sterility assurance level for some medical devices
- Continue to partner with industry stakeholders (e.g. EtO innovation challenge)
- Facilitate collaboration with industry and communications with stakeholders
- Enhance FDA's ability to respond to device shortages by incorporating processes currently used with drug shortages, if appropriate.
- Look at incentive structures that may help to catalyze industry EtO activities
- Strongly consider removing IFUs from devices that are being sterilized
- Work collaboratively with other government entities, on the federal as well as state level
- Explore alternative modalities in niche device categories where these alternatives can work effectively
- Request AAMI work group to review industrial sterilization

Next Steps

- Announce applications selected for the innovation challenge
- Communicate Advisory Committee summary
- Determine action items from Advisory Committee Meeting
- Continue engagement with firms regarding potential shortages
  - Objective: Mitigate shortages via real-time review of sterilization approaches using benefit/risk
- Continue to have SMEs submit informational q-subs for alternative sterilization methods
  - Objective: Enhance FDA's understanding of available methods to inform decision making


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