FDA Sterigenics Facility Closure and Ethylene Oxide Update

HICPAC
May 16, 2019
CDRH
Presentation Outline

• Framing
• Quick Update on CDRH activities
  – Shortages
  – Communications
  – Congressional
  – Stakeholder engagement
• Exploration of Key Questions
• Next Steps
• 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)
• Sterigenics has 9 sites in the US and there are approximately 155 contract sterilizers in US
• 1 contract sterilizer is closing by the end of 2019 (Viant)
• Contract sterilizers have limited ability to increase capacity
Framing (cont.)

- Illinois Department of Public Health Report regarding cancer risk
- Ongoing surveillance and CDC research
- Overarching Activities
  - Response
  - Proactive/forward leaning
Shortages Assessment

• Identification and outreach to device manufacturers

• Information gathering via healthcare organizations, distributor groups, and trade organizations
  – To understand potential supply chain disruptions

• Confirmed product shortage:
  – Bivona Tracheostomy Tubes (Smiths Medical released newly sterilized products the week of April 22, 2019)

• Shortages mailbox
Communications

• 2/27/19 Letter to industry regarding site changes and reporting shortage concerns
• 3/26/19: Webpage launch
• 3/26/19: Commissioner Shortage Statement
• 4/12/19: CDRH Center Director Bivona Tracheostomy Tube Temporary Shortage Statement
Congressional

- 3/15/19: IL delegation briefing
- 3/25/19: MN delegation briefing
- 4/11/19: IL delegation (Senate) sends letter to Commissioner asking about FDA actions to evaluate EtO alternatives
- 4/24/19: IL delegation (House members) sends letter to Commissioner asking about FDA actions to evaluate EtO alternatives
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
Questions the FDA is Exploring

• Can a reduction in the amount of EtO used to sterilized medical devices achieve Sterility Assurance?
• Are their alternative methods to EtO sterilization that can adequately sterilize medical devices?
Next Steps

• Launch an Innovation Challenge (Summer 2019)
  – Objective: Encourage EtO reduction and alternatives

• Advisory Committee Meeting (Fall 2019)
  – Objective: Obtain stakeholder feedback regarding challenges and opportunities for EtO reduction and the use of alternative strategies to inform FDA decision making

• Continue engagement with firms regarding potential shortage (Continuous)
  – 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 (Continuous)
  – Objective: Enhance FDA’s understanding of available methods to inform decision making