U.S. FOOD & DRUG ADMINISTRATION

Welcome To Today's Program

Thanks for joining us!
We'll get started in a few minutes

Today's Topic:
Medical Device Sterilization Town Hall:
FDA Activities and Challenges in Reducing Reliance on Ethylene Oxide

January 26, 2024

U.S. FOOD & DRUG ADMINISTRATION

Medical Device Sterilization Town Hall:

FDA Activities and Challenges in Reducing Reliance on Ethylene Oxide

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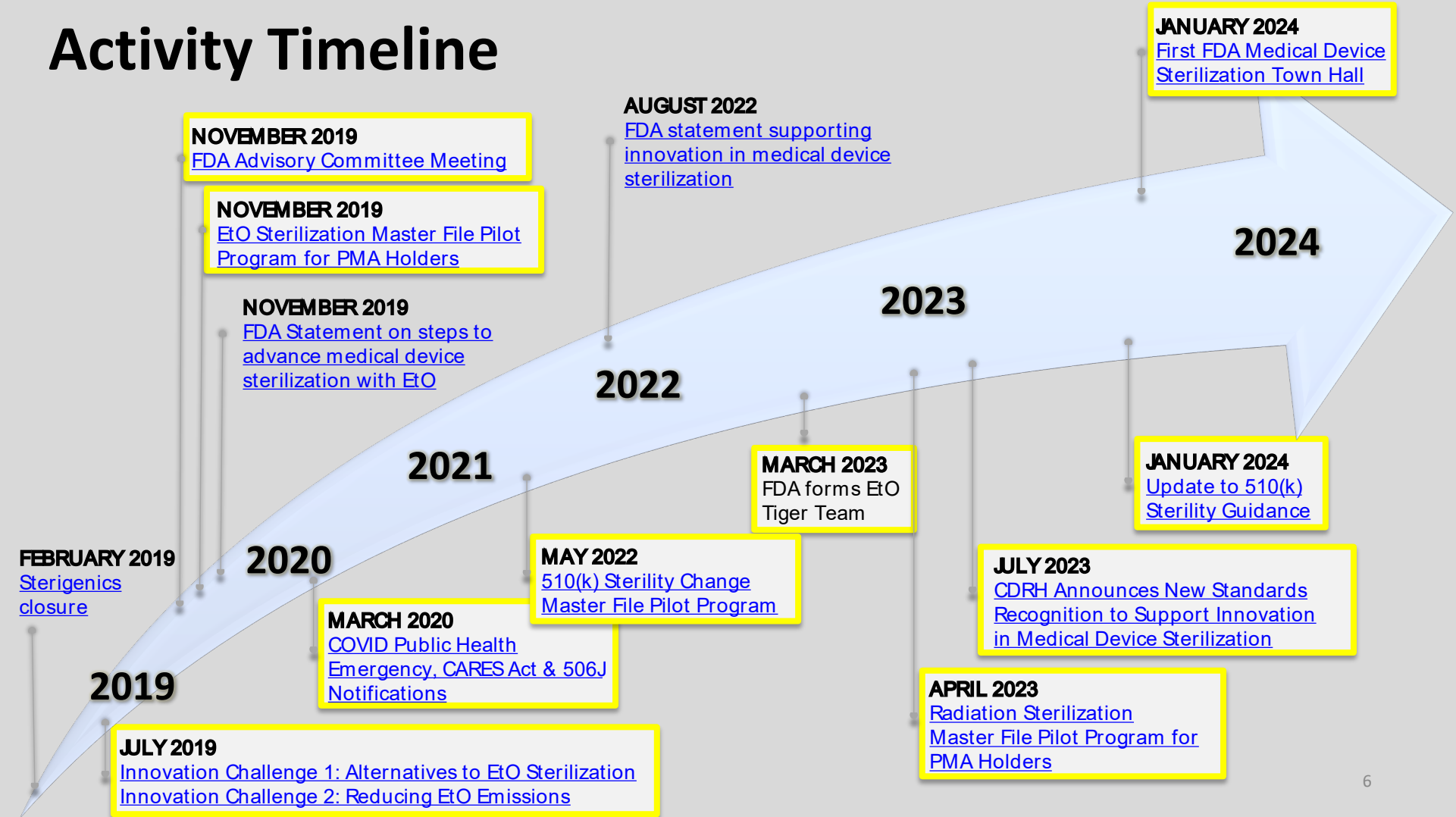
What we heard from you last time

Learning Objectives

- Describe 2019 Advisory Committee recommendations and FDA's early actions to mitigate the impact of the potential loss of EtO sterilization capacity in the US
- Describe FDA's understanding of opportunities and challenges to using alternative sterilization modalities
- Describe recent activities to reduce overall EtO reliance while maintaining a resilient supply of sterilized medical devices

Activity Timeline



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Regulatory Advisor
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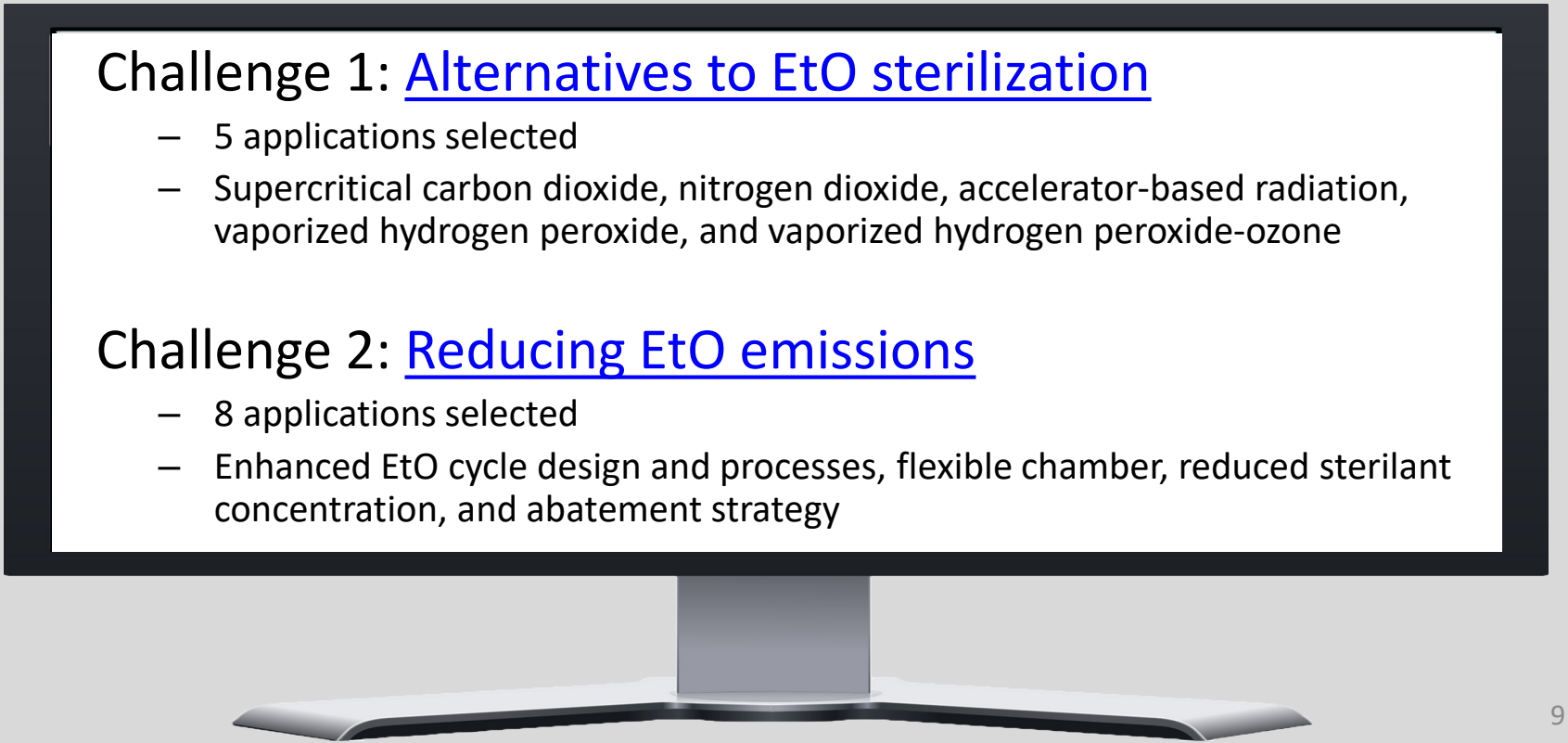
Early Actions and Recommendations from the 2019 Advisory Committee Meeting

Partnering with Industry Stakeholders: FDA Innovation Challenges



Challenge 1: Alternatives to EtO sterilization

- 5 applications selected
- Supercritical carbon dioxide, nitrogen dioxide, accelerator-based radiation, vaporized hydrogen peroxide, and vaporized hydrogen peroxide-ozone

Challenge 2: Reducing EtO emissions

- 8 applications selected
- Enhanced EtO cycle design and processes, flexible chamber, reduced sterilant concentration, and abatement strategy

2019 Advisory Committee Meeting Key Recommendations

- Continue to partner with industry stakeholders (e.g., EtO Innovation Challenge)
- Consider incentive structures that may help catalyze industry EtO activities (e.g., Sterility Master File Pilot Programs)
- Consider risk-based sterility assurance levels for some medical devices
- Enhance FDA's ability to respond to device shortages by incorporating processes currently used with drug shortages, if appropriate
- Remove paper instructions from devices that are being sterilized, where possible
- Explore alternative sterilization modalities in devices where these alternatives can work effectively
- Leverage work with standards to advance alternative sterilization methods
- Work collaboratively with other government entities, on the federal and state level
- Facilitate collaboration with industry and communications with stakeholders

Incentive Structures: Sterility Master File Pilot Programs

- EtO Sterilization Master File Pilot Program for PMA Holders (2019)
  - allows companies that sterilize single-use medical devices using fixed chamber EtO to submit a Master File when making certain changes between sterilization processes and facilities that reduce the amount of EtO concentrations used to sterilize medical devices
- 510(k) EtO Sterility Change Master File Pilot Program (2022)
  - allows companies to make changes to a cleared medical device's sterilization method from a fixed chamber EtO sterilization cycle to the sterilization method described in the Master File
- Radiation Sterilization Master File Pilot Program (2023)
  - allows companies to make changes to or advance alternative ways to sterilize approved medical devices using radiation (x-ray and electron beam)

Sterilization for Medical Devices / Sterilization Master File Pilot Programs

Lisa Simone, PhD
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Ramping Up Effort for Forward Leaning Approaches

CDRH EtO Tiger Team

Goal: Support efforts to reduce reliance on EtO for medical device sterilization

- Cross CDRH involvement to foster nimble response in advancing sterilization innovation
- Expertise in regulatory science, regulatory review, policy, supply chain, incident response
- Integrate with broader CDRH EtO-related activities
- External stakeholder engagement
- State and federal engagement
- Medical Device Sterilization Town Hall Series

CDRH EtO Tiger Team

CDRH Offices Represented

OST: Office of Strategic Partnerships and Technology Innovation

ORR: Office of Readiness & Response

OSCR: Office of Supply Chain Resilience

OPEQ: Office of Product Evaluation and Quality

OSEL: Office of Science and Engineering Laboratories

OP: Office of Policy

OCD: Office of the Center Director

Stakeholder Outreach: Overview

Goal: Understand opportunities and challenges to using alternative sterilization modalities

- Engage with device manufacturers, sterilizers and professional organizations
  - Interest/activity in using alternative gaseous or radiation-based sterilants for devices where EtO currently used
  - Challenges transitioning from EtO

Stakeholder Feedback

- Some straightforward successes shifting sterilization modalities
- Transitioning from EtO to another modality has technical, logistical and regulatory challenges
- EtO transition plans are varied with most being long-term and requiring significant resources

Stakeholder Outreach: How can FDA Help?

- Aid industry understanding of regulatory review
- Streamline regulatory review where possible
- Coordinate with other international regulators
- Collaborate with industry on
  - challenging technical topics
  - educational opportunities

LCDR Scott Steffen, PhD
Senior Program Management Officer / EtO Incident Lead
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Office of Strategic Partnerships and Technology Innovation

Recent Activities, Goals and Opportunities

Industry Activities, Data Sharing and Collaboration

- Reducing EtO usage, actively seeking alternative modalities
- Standards-based collaborative activities
- Voluntary reporting of medical device shortages
  - Submit a 506J Notification using the webform or to CDRHManufacturerShortage@fda.hhs.gov
- Data needs when revisiting sterilization goals and methods
- Further opportunities to interact

Recent FDA Activities

- Radiation Sterilization Master File Pilot Program for PMA holders (2023)
- Leveraging standards to advance alternate methods: Standards List 60 recognitions (2023)
  - ISO 22441:2022
  - AAMI TIR17:2017/(R)2020
  - AAMI TIR104:2022
- 510(k) Sterility Guidance update (2024)
- Engagement in conferences and workshops
- Sterility focal point program harmonizing review practices across review offices

CDRH Announces New Standards Recognition to Support Innovation in Medical Device Sterilization

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The following is attributed to Suzanne Schwartz, M.D., M.B.A., director, Office of Strategic Partnerships and Technology Innovation, CDRH

Today, the FDA's Center for Devices and Radiological Health (CDRH) is announcing additional steps to advance innovation in medical device sterilization. CDRH has updated its Recognized Consensus Standards database to include the complete recognition of one sterilization standard (ISO 22441:2022) and two Technical Information Reports (AAMI TIR104:2022 and AAMI TIR17:2019/(R)2020).

Progress on Recommendations

- Incentive structures to catalyze industry activity
- Leveraging standards to advance alternate methods
- Explore alternative modalities
- Enhance FDA's ability to respond to device shortages
- Work collaboratively with state and federal entities
- Facilitate collaboration with industry
- Communications with stakeholders

Resources

Slide Number	Cited Resource	URL
6	Sterigenics closure	www.epa.gov/il/sterigenics-willowbrook-facility
6	Innovation Challenge 1: Alternatives to EtO Sterilization	www.fda.gov/medical-devices/general-hospital-devices-and-supplies/fda-innovation-challenge-1-identify-new-sterilization-methods-and-technologies
6	Innovation Challenge 2: Reducing EtO Emissions	www.fda.gov/medical-devices/general-hospital-devices-and-supplies/fda-innovation-challenge-2-reduce-ethylene-oxide-emissions
6	FDA Advisory Committee Meeting	www.fda.gov/advisory-committees/advisory-committee-calendar/november-6-7-2019-general-hospital-and-personal-use-devices-panel-medical-devices-advisory-committee
6	EtO Sterilization Master File Pilot Program for PMA Holders	www.federalregister.gov/documents/2019/11/26/2019-25631/center-for-devices-and-radiological-health-ethylene-oxide-sterilization-master-file-pilot-program
6	FDA Statement on steps to advance medical device sterilization with EtO	www.fda.gov/news-events/press-announcements/statement-new-steps-advance-innovation-medical-device-sterilization-ethylene-oxide
6	COVID Public Health Emergency, CARES Act & 506J Notifications	www.fda.gov/medical-devices/medical-device-safety/medical-device-supply-chain-and-shortages
6	FDA statement supporting innovation in medical device sterilization	www.fda.gov/news-events/press-announcements/fda-continues-efforts-support-innovation-medical-device-sterilization
6	510(k) Sterility Change Master File Pilot Program	www.federalregister.gov/documents/2022/05/20/2022-10925/medical-devices-510k-sterility-change-master-file-pilot-program

Resources

Slide Number	Cited Resource	URL
6	Radiation Sterilization Master File Pilot Program for PMA Holders	www.fda.gov/medical-devices/medical-devices-news-and-events/cdrh-announces-radiation-sterilization-master-file-pilot-program
6	CDRH Announces New Standards Recognition to Support Innovation in Medical Device Sterilization	www.fda.gov/medical-devices/medical-devices-news-and-events/cdrh-announces-new-standards-recognition-support-innovation-medical-device-sterilization
6	Update to 510(k) Sterility Guidance	www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled
6	FDA Medical Device Sterilization Town Hall Series	www.fda.gov/medical-devices/workshops-conferences-medical-devices/medical-device-sterilization-town-hall-overview-sterilization-landscape-and-role-ethylene-oxide
9	Alternatives to EtO sterilization	www.fda.gov/medical-devices/general-hospital-devices-and-supplies/fda-innovation-challenge-1-identify-new-sterilization-methods-and-technologies
9	Reducing EtO emissions	www.fda.gov/medical-devices/general-hospital-devices-and-supplies/fda-innovation-challenge-2-reduce-ethylene-oxide-emissions
11	Sterilization Master File Pilot Programs	www.fda.gov/medical-devices/general-hospital-devices-and-supplies/sterilization-medical-devices#MasterFile
21	Submitting a 506J using the webform	fda-cdrh.my.salesforce-sites.com/shortages/
27	Sterilization for Medical Devices	www.fda.gov/medical-devices/general-hospital-devices-and-supplies/sterilization-medical-devices

Summary

- Since FDA's 2019 Advisory Committee Meeting, FDA and industry have worked to reduce EtO use and encourage the advancement of EtO alternatives
- The CDRH-wide EtO Tiger Team was launched to further support efforts to reduce reliance on EtO use for medical devices
- FDA welcomes additional opportunities to engage with industry going forward

Next Town Hall

Date: Wednesday, February 7, 2024

Time: 3:00 – 4:00 pm ET

Potential Topic:

- Premarket considerations for sterilization-related submissions

A new section has been added to our Sterilization for Medical Devices webpage and includes town hall dates and links to town hall materials.

Medical Device Sterilization Town Hall Series

www.fda.gov/medical-devices/general-hospital-devices-and-supplies/sterilization-medical-devices#town-halls


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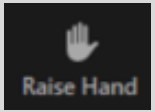
Additional Panelists

Suzanne Schwartz, MD, MBA
Director

Office of Strategic Partnerships and Technology Innovation

Tammy Beckham, DVM, PhD
Office Director
Office of Supply Chain Resilience
Office of Strategic Partnerships and Technology Innovation

Let's Take Your Questions and Comments

- **To ask a question/share a comment:**
  

  - Raise your hand in Zoom
  - Moderator will announce your name and invite you to speak
  - Unmute yourself when prompted in Zoom to speak
- **When asking a question/sharing a comment:**
  - Keep question/comment as short as possible
  - No questions about specific submissions
- **After question/comment is addressed:**
  - Mute yourself and lower your hand
  - If you have another question/comment - raise your hand again

Additional questions/comments about today's topic

- Email: MedicalDeviceSterilization@fda.hhs.gov

Thanks for Joining Today!

- **Presentation and Transcript will be available at CDRH Learn**
  - www.fda.gov/Training/CDRHLearn
- **Additional questions/comments about today's presentation**
  - Email: MedicalDeviceSterilization@fda.hhs.gov
- **Upcoming Town Halls & Webinars**
  - www.fda.gov/CDRHWebinar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