Welcome to Today’s FDA/CDRH Webinar

Thank you for your patience while we sign in all of today’s participants.

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FDA Innovation Challenge: Devices to Prevent and Treat Opioid Use Disorder

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Agenda

• The Opioid Epidemic
• FDA’s Efforts to Combat the Opioid Crisis
• Overview of the Innovation Challenge
• Tips for Potential Applicants
• Resources
• Questions
THE OPIOID EPIDEMIC BY THE NUMBERS

IN 2016...

116
People died every day from opioid-related drug overdoses

42,249
People died from overdosing on opioids²

170,000
People used heroin for the first time¹

948,000
People used heroin¹

2.1 million
People had an opioid use disorder¹

2.1 million
People misused prescription opioids for the first time¹

17,087
Deaths attributed to overdosing on commonly prescribed opioids²

19,413
Deaths attributed to overdosing on synthetic opioids other than methadone²

15,469
Deaths attributed to overdosing on heroin²

504 billion
In economic costs³

Sources: ¹ 2016 National Survey on Drug Use and Health, ² Mortality in the United States, 2016 NCHS Data Brief No. 293, December 2017, ³ CEA Report: The underestimated cost of the opioid crisis, 2017
HHS 5-POINT STRATEGY TO COMBAT THE OPIOIDS CRISIS

1. **Better** addiction prevention, treatment, and recovery services
2. **Better** data
3. **Better** pain management
4. **Better** targeting of overdose reversing drugs
5. **Better** research

HHS.GOV/OPIOIDS
1. Decreasing Exposure & Prevent New Addiction

- Appropriate Dose/Duration Labeling
- Appropriate Packaging, Storage, and Disposal
- Health Care Provider Education

2. Supporting the Treatment of Those With Opioid Use Disorder

- Naloxone
- Medication Assisted Treatment (MAT)

3. Fostering the Development of Novel Pain Treatment Therapies

- Partnerships & Meetings
- Abuse Deterrent Formulations (ADFs)
- Pain Treatment Alternatives

4. Improving Enforcement & Assessing Benefit-Risk

- Improving Enforcement
- Assessing Benefit-Risk
In the past few years, FDA has cleared, granted, or approved more than 200 devices related to the treatment or management of pain.

Includes 10 with new or novel technologies, such as brain and spinal cord stimulators to relieve pain and reduce the need for opioid drugs to patients suffering from either acute or chronic pain.

The FDA also recently granted a new indication to an electric stimulation device for use in helping to reduce the symptoms of opioid withdrawal.
Overview of the Innovation Challenge

Challenge Goals:

• Innovative and creative approaches to the use of medical devices in combatting the U.S. opioid crisis
• Development of non-opioid treatments for acute and chronic pain
• Expedited development and review of innovative, safe and effective medical devices to help prevent and treat opioid use disorder
Overview of the Innovation Challenge

Eligibility

• Any medical device that prevents or treats opioid use disorder, including:
  o Diagnostic Devices
  o Therapeutic Devices
  o Digital Health Technologies (e.g., mobile medical apps)
  o Combination Products: primary mode of action is by the device

• Medical devices at any stage of development are eligible

• U.S.-based and foreign applicants are eligible to apply

• Per federal law, foreign firms will need a U.S. representative to market a device in the U.S.
Overview of the Innovation Challenge

Challenge Submissions Should Describe:

- Intended use
- Novelty of the medical device/concept
- Development plan for the medical device
- Development team
- Anticipated benefit of the device
- Impact on public health as compared to other available alternatives
Overview of the Innovation Challenge

Other Factors the FDA will Consider:

• Feasibility of device/concept
• Potential impact of FDA participation in development
Overview of the Innovation Challenge

Challenge Timeline

• Applications must be submitted electronically to FDA by September 30, 2018, through the dedicated mailbox: CDRH-Innovation-Opioid@fda.hhs.gov

• We intend to announce applications selected for the challenge in November 2018
Overview of the Innovation Challenge

What to Expect If Your Application is Selected:

• Development Phase
• Premarket Application
• Expedited Premarket Review
Tips for Potential Applicants

• You may submit multiple applications if you have more than one eligible device

• FDA will not review device applications prior to submission deadline or provide specific advice to challenge applicants. If your device/concept meets the challenge criteria, please submit an application.

• There is no official application form. The application format is outlined on the challenge website.
Resources

• Devices to Prevent and Treat Opioid Use Disorder Innovation Challenge Webpage (includes application format)
  http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProducts andTobacco/CDRH/CDRHInnovation/ucm609082.htm

• Device Advice: Comprehensive Regulatory Assistance
  https://www.fda.gov/medicaldevices/deviceregulationandguidance/

• Mobile Medical Applications Webpage
  https://www.fda.gov/medicaldevices/deviceregulationandguidance/

• Breakthrough Devices Webpage
  https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/ucm441467.htm
Questions?

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Slide Presentation, Transcript and Webinar Recording will be available by August 2, http://www.fda.gov/training/cdrhlearn
Under the Heading: Specialty Technical topics; Subheading: Neurological Device

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