

**FOOD AND DRUG ADMINISTRATION (FDA)**  
Center for Drug Evaluation and Research (CDER)

***Joint Meeting of the Nonprescription Drugs Advisory Committee (NDAC) and the  
Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC)***

February 15, 2023

**AGENDA**

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*The committees will discuss supplemental new drug application 208411/S-006, for NARCAN (naloxone hydrochloride) nasal spray, 4 mg/0.1 mL, submitted by Emergent BioSolutions Inc. NARCAN is proposed for nonprescription treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression. The issues for discussion will be on the adequacy of the data supporting the nonprescription application. This product represents a potential first in class product in a new therapeutic category for nonprescription drugs.*

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9:00 a.m.	Call to Order	<b>Maria C. Coyle, PharmD, FCCP, BCPS, BCACP, CLS</b> Chairperson, NDAC
9:15 a.m.	Introduction of Committee and Conflict of Interest Statement	<b>Moon Hee V. Choi, PharmD</b> Designated Federal Officer, NDAC
9:20 a.m.	FDA Opening Remarks	<b>Jody Green, MD</b> Deputy Director for Safety Division of Nonprescription Drugs I (DNPDI) Office of Nonprescription Drugs (ONPD) Office of New Drugs (OND), CDER, FDA
9:35 a.m.	<b>APPLICANT PRESENTATIONS</b>	<b>Emergent BioSolutions, Inc.</b>
	Introduction	<b>Manish Vyas, BSc, EMBA</b> Senior Vice President, Regulatory Affairs Emergent BioSolutions
	NARCAN® Nasal Spray 4 mg and the OTC Development Program	<b>Gay Owens, PharmD, MBA</b> Global Medical Affairs Lead, Opioid Antidote Emergent BioSolutions
	Medical Need for OTC Nasal Naloxone	<b>Scott Hadland, MD, MPH, MS</b> Chief, Division of Adolescent and Young Adult Medicine Massachusetts General Hospital – Harvard Medical School
	Human Factors Study	<b>Sarah Farnsworth, PhD</b> Vice President, Scientific Affairs PEGUS Research

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**AGENDA (cont.)**

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**APPLICANT PRESENTATIONS (CONT.)**

NARCAN® Benefit-Risk Overview & Conclusion      **Manish Vyas, BSc, EMBA**

10:35 a.m.      Clarifying Questions

10:55 a.m.      **BREAK**

11:10 a.m.      **FDA PRESENTATIONS**

Regulatory Overview of Narcan Nasal Spray & Postmarketing Safety Data      **Dorothy Chang, MD**  
Senior Physician  
DNPD I, ONPD, OND, CDER, FDA

OTC Naloxone Model Drug Facts Label Comprehension Study      **Barbara Cohen, MPA**  
Social Science Analyst  
Division of Nonprescription Drugs II  
ONPD, OND, CDER, FDA

Human Factors Validation Study      **Millie Shah, PharmD, BCPS**  
Senior Pharmacist  
Division of Medication Error Prevention and Analysis II, Office of Surveillance and Epidemiology  
CDER, FDA

12:10 p.m.      Clarifying questions for FDA

12:30 p.m.      **LUNCH**

1:30 p.m.      **OPEN PUBLIC HEARING**

3:00 p.m.      Charge to the Committee      **Jody Green, MD**

3:10 p.m.      Questions to the Committee/Committee Discussion

4:00 p.m.      **BREAK**

4:10 p.m.      Questions to the Committee/Committee Discussion (cont.)

5:30 p.m.      **ADJOURNMENT**