# PRE-SUBMISSION MEETINGS WITH THE OFFICE OF SCIENCE

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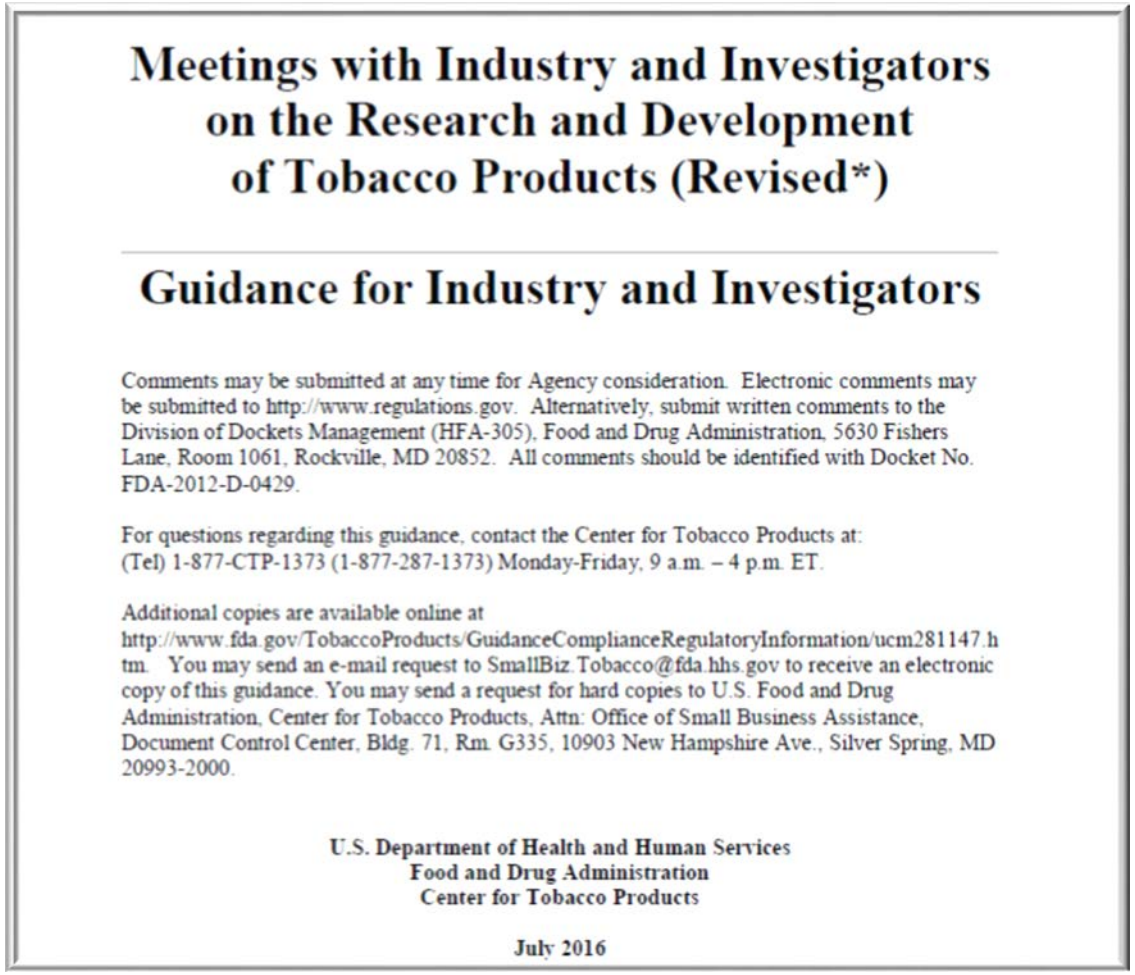
*Disclaimer: This is not a formal dissemination of information by FDA and does not represent Agency position or policy.*

# AGENDA

- Meeting Resources and Process Overview
- Meeting Request
  - Considerations when Preparing a Meeting Request
  - OS Evaluation of a Meeting Request
- Meeting Process: Outcomes and Communications
- Program Updates: Performance Goals

# MEETING RESOURCES: GUIDANCE



**Meetings with Industry and Investigators on the Research and Development of Tobacco Products (Revised*)**

**Guidance for Industry and Investigators**

Comments may be submitted at any time for Agency consideration. Electronic comments may be submitted to http://www.regulations.gov. Alternatively, submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. All comments should be identified with Docket No. FDA-2012-D-0429.

For questions regarding this guidance, contact the Center for Tobacco Products at: (Tel) 1-877-CTP-1373 (1-877-287-1373) Monday-Friday, 9 a.m. – 4 p.m. ET.

Additional copies are available online at http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm281147.htm. You may send an e-mail request to SmallBiz.Tobacco@fda.hhs.gov to receive an electronic copy of this guidance. You may send a request for hard copies to U.S. Food and Drug Administration, Center for Tobacco Products, Attn: Office of Small Business Assistance, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-2000.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products

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**Full Document: Guidance for Industry and Investigators - Meetings with Industry and Investigators on the Research and Development of Tobacco Products (Revised*)**

- What is the scope of this guidance?
- Which FDA staff would likely attend this meeting?
- How do I request a meeting?
- When should I submit my meeting request?
- What should I include in my meeting request?
- How will FDA to respond to my request?
- If FDA denies my initial meeting request, can I resubmit my request?
- Could FDA decide that a face-to-face meeting or teleconference is unnecessary?
- Who will be my point of contact for the meeting?
- Is there any additional information that I should submit prior to the scheduled meeting?
- What should I include in my meeting information package?
- Where do I send my meeting requests and meeting information packages?
- What if I am unable to provide adequate supporting documentation in my meeting information package no later than 45 days prior to the scheduled meeting?
- If my initial meeting request is postponed or canceled, can I resubmit my request?
- What, if anything, should I bring to the meeting?
- How will the meeting be conducted?
- Will FDA provide any documentation to summarize the meeting?
- What should I do if I have a question or concern regarding the official meeting minutes?
- Can I submit or discuss confidential information with FDA prior to, during, or after the meeting?

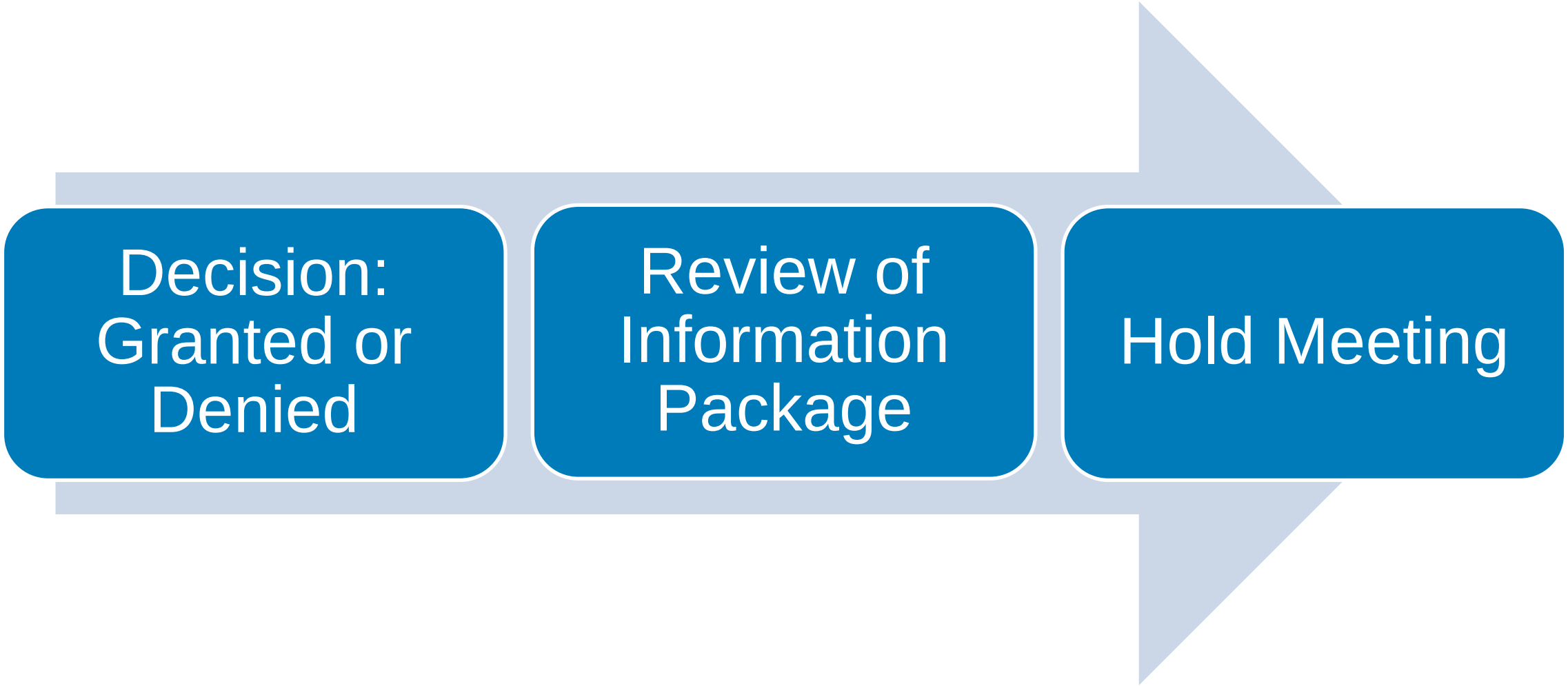
# MEETING RESOURCES: TOBACCO COMPLIANCE WEBINAR

Meeting with Office of Science (40:11) ***Download Slides***

**Table of Contents**



# MEETING REQUEST PHASES



# CONSIDERATIONS WHEN PREPARING A MEETING REQUEST

# EXAMPLE: MEETING PURPOSE AND OBJECTIVES

## Pre-Submission Meetings

Purpose: A pre-PMTA meeting to discuss respiratory endpoints in a clinical study

Objective: Gain FDA feedback on relevancy of biomarker X on endpoint X

Objective: Understand sampling and inspection requirements for a PMTA for product X

## Informational Meetings

Purpose: A discussion of ENDS system failure and battery hazards

Objective: Present novel feature X designed to prevent overheating in ENDS

Objective: Present overview of manufacturing processes for ENDS batteries

# EXAMPLE: MEETING AGENDA

Introduction – 5 minutes [Speaker 1]

Product Overview – 5 minutes [Speaker 2]

Scientific Discussion – 20 minutes [Speaker 3]

- Biomarker A
- Endpoint X

Regulatory Process Discussion – 25 minutes [Speaker 4]

- Product Sampling
- Clinical and Manufacturing Inspection

Review of Discussion/Conclusion – 5 minutes [Speaker 5]

# MEETING ATTENDEES

Name

Title

Position

Credentials

Company

FDA will make the final determination of FDA staff assigned to the meeting request.

# MEETING FORMAT

Face-to-Face

Teleconference

Written Response Only

FDA will make the final determination on the meeting date and format; the format may differ from that which was requested.

# SUPPORTING INFORMATION

## Meeting Request

- Preliminary list of specific questions

## Final Meeting Information Package

- 45 days prior to the scheduled meeting or within the meeting request
- Final list of specific questions
- Current summary data relevant to your product(s)
  - e.g., product composition, clinical or nonclinical data summary
- Description of the design, conduct, and analysis of relevant studies
  - some quantification needed (i.e., avoid merely describing a result as “significant”)
- Full study reports or detailed data generally not appropriate

FDA will generally hold meetings no sooner than 45 days after receipt of your final meeting information package.

# FDA EVALUATION OF A MEETING REQUEST

# MEETING REQUEST EVALUATION

Does the meeting request follow and contain items outlined in the Guidance?

Is the Meeting Necessary or Appropriate?

Is the Meeting Timely?

If the answer is yes to all of the above questions, the meeting may be granted.

# MEETING REQUEST EVALUATION

## FDA does not use meetings to:

- provide response to the sufficiency of scientific evidence
- furnish scientific expertise
- perform data analyses
- make premarket decisions
- establish binding agreements

# MEETING PROCESS: OUTCOMES AND COMMUNICATIONS

# MEETING PROCESS: DECISION LETTER

## Expected Outcome of a Meeting Request

- Denied

or

- Granted

# MEETING PROCESS: REVIEW

## Expected Outcome of FDA's Review of the Information Package

- Final Response
  - FDA issues a Written Response letter only as previously communicated

or

- Preliminary Response
  - Applicant may choose to cancel the meeting if no further clarification is needed

# MEETING PROCESS: MEETING

## Expected Outcome of the Meeting

- Minutes
- Post Meeting Correspondence (if applicable)

FDA intends to provide meeting minutes within 45 days of the meeting.

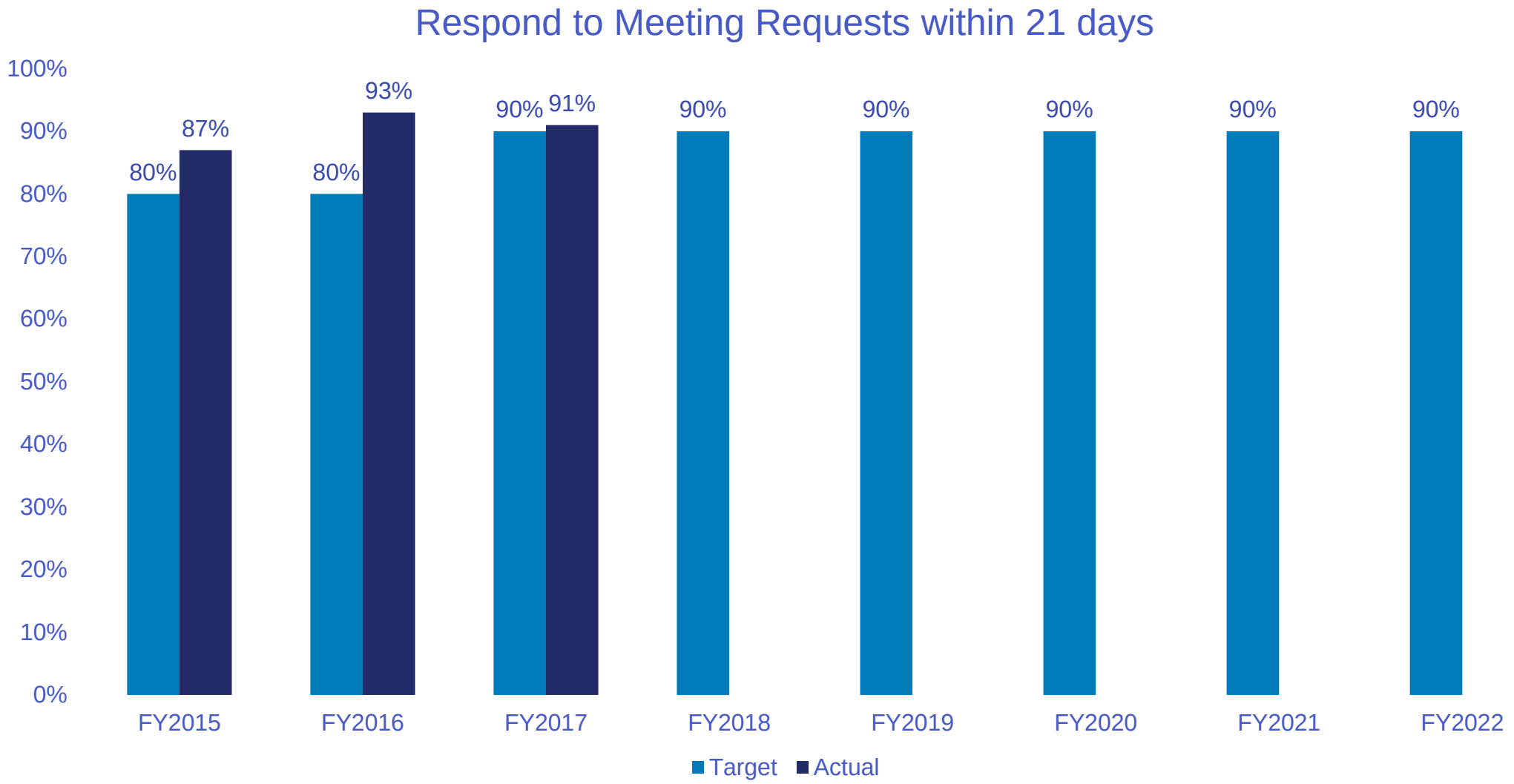
# MEETING PROCESS: WITHDRAWAL AND CANCELATION

- Withdraw a Meeting Request
  - Applicant determines a meeting is no longer needed prior to receiving a Meeting Decision Letter

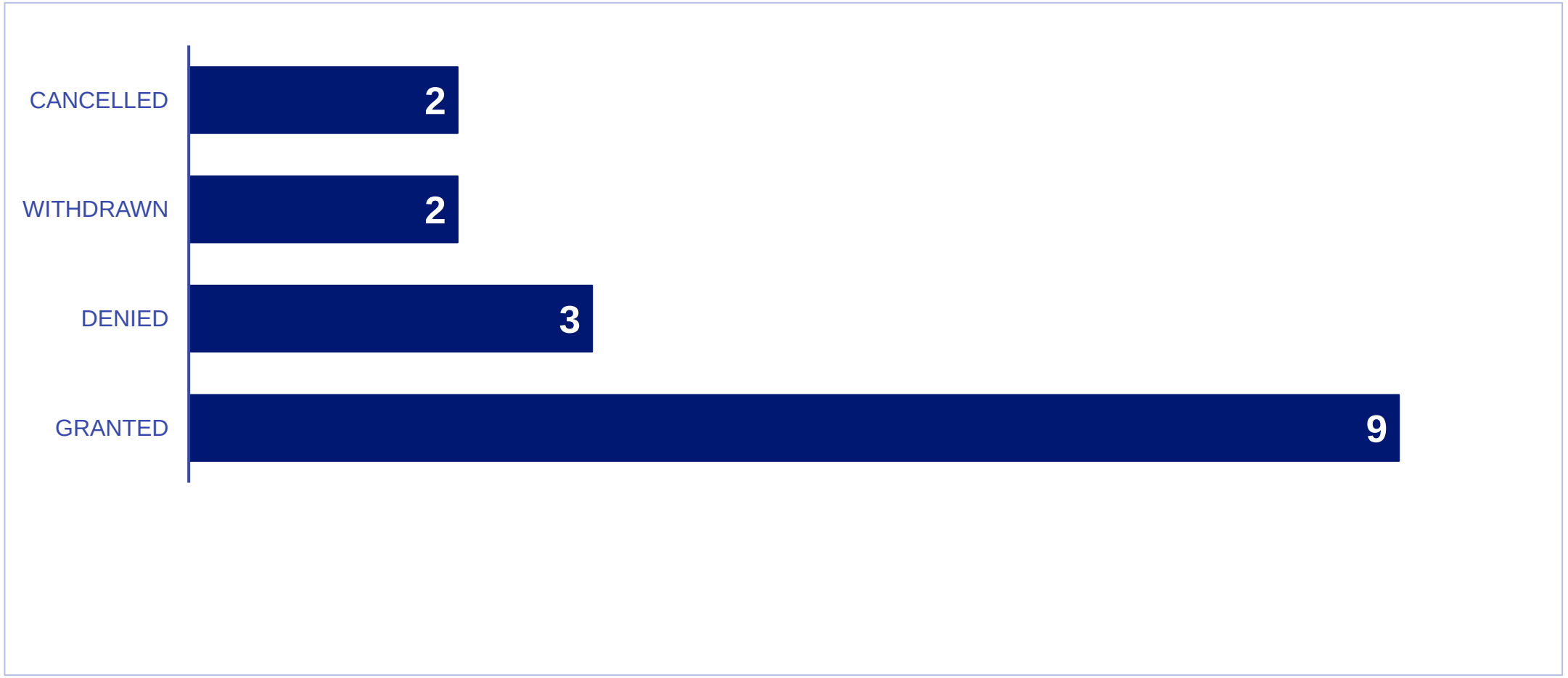
- Cancel a Meeting
  - Applicant or FDA determine a meeting is no longer needed after the Meeting has been granted

# PROGRAM UPDATES

# PERFORMANCE GOAL: CTP RESPONSE TIMEFRAME



# FY 2018 STATUS OF OS MEETINGS



# THANK YOU