



# **A FDA Perspective on Pediatric Neurologic Devices**

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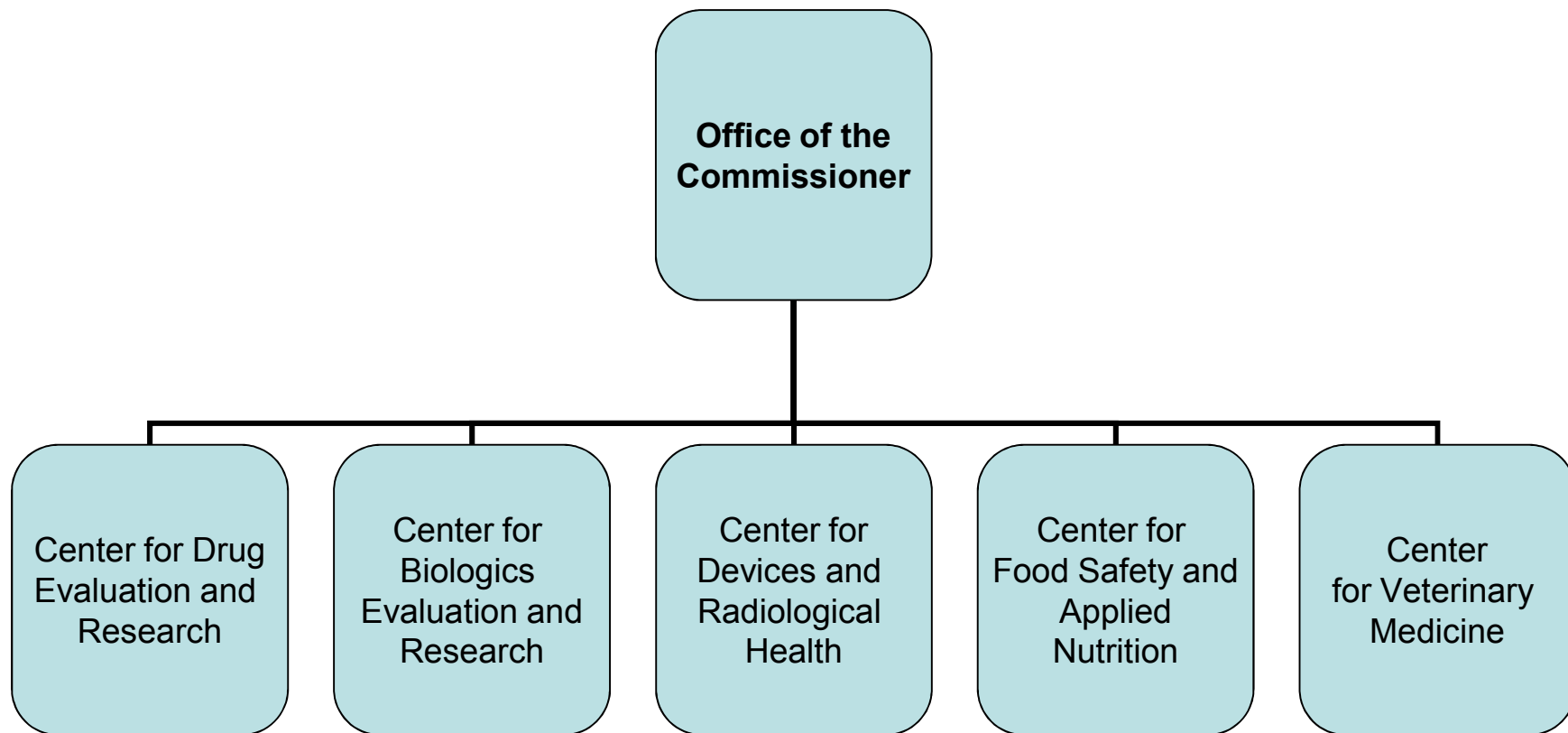
## Outline

- FDA Mission & Organization
- The Center for Devices and Radiological Health
- Considerations for Safe and Effective Use of Pediatric Neurologic Devices
- ASK CHILDREN Study
- Final Thoughts



# Organization

## U.S. Food and Drug Administration





## FDA Mission Statement

The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.



# Center for Devices and Radiological Health

The Center for Devices and Radiological Health (CDRH) is responsible for regulating firms who manufacture, repackage, relabel, or import medical devices sold in the United States.



## Definition of a Medical Device

A device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro agent, or other similar or related article, including a component, part, or accessory, which is recognized in the National Formulary, or the US Pharmacopeia, or any supplement to them, intended for use in the diagnosis of disease, or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which



# Center for Devices and Radiological Health

*A Few Regulatory Pathways...*

- PreMarket Approval (PMA)
- Premarket Notification (510(k))
- Humanitarian Device Exemption (HDE)



# Center for Devices and Radiological Health

*Mechanism for Collecting Data for a Device Submission*

- Investigational Device Exemption (IDE)



## **Class II Neurologic Devices (1994-2003)\***

- Deep Brain Stimulator (n=1);
- Cochlear Implant (n=4);
- Vagus Nerve Stimulator (n=1);
- Spinal Peripheral Nerve Stimulator (n=2).

\* Based upon devices evaluated in Peña et al., 2004; 63:1163-1167.



# Some Considerations for the Safe and Effective Use of Pediatric Neurologic Devices\*

- Brain Development;
- Physical Growth;
- Surgery; and
- Human Factors.

\* Based upon devices evaluated in Peña et al., 2004; 63:1163-1167.



## One Example

# Deep Brain Stimulator for Primary Dystonia\*

Risks Considered for Use in Children:

- Lead strain/fracture due to trunk growth;
- Lead migration due to head growth;
- Neurostimulator interference due to closer placement in smaller patients; and
- Post-implant, long-term risks due to return to normal activities (e.g. sports).

\* Based upon devices evaluated in Peña et al., 2004; 63:1163-1167.



## One Example

# Deep Brain Stimulator for Primary Dystonia\*

### Mitigation Techniques:

- Labeling for use in children where head physical growth is 90% complete;
- Labeling for regular, post-op follow-up visits, including consideration for replacement components at other elective surgeries;
- Lead stimulator reprogramming to optimize performance; and
- Alternative bilateral placement of neurostimulators.

\* Based upon devices evaluated in Peña et al., 2004; 63:1163-1167.



## **Importance for Pediatric Clinical Data**

- Often pediatric data is not available;
- Adult data not relevant/sufficient;
- Bench/Animal data not relevant/sufficient;  
Design modifications require  
evidence/verification; and
- Need for pediatric specific treatment strategy.



# ASK CHILDREN Study

Assess **S**pecific **K**inds of **C**HILDREN Challenges for Neurologic Devices **S**TUDY

## FDA PAC

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## **ASK CHILDREN Study Objectives**

- Collect self reported data in children with neurologic devices to identify human factors, safety, usability, and adverse events important for future products, including the identification of early postmarket challenges;
- Plan, organize, and execute a public meeting of patients and subject matter experts to hear and discuss self reported data collected; and
- Establish a framework of science-based recommendations involving the very patients we are trying to help.



# Final Thoughts