

The Office of Regulatory Policy: Role in CDER and CDER's COVID-19 Pandemic Response

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Learning Objectives

- Describe how regulatory policy guides decision making in CDER
- Explain the organization and function of the Office of Regulatory Policy (ORP) and ORP's role in CDER
- Provide representative examples of our contributions to CDER's COVID-19 pandemic response

Regulatory Policy at CDER



- Regulatory policy provides a framework to guide decision making in CDER
- Helps ensure that our decisions and policy are consistent with statutes, regulations, and other decisions
- Program offices and Center-level policy shops

What is the Office of Regulatory Policy?



- Overarching regulatory policy shop at CDER – development, oversight, and leadership
- Initiate, develop, and review regulations, guidance, and other policy related to the regulation of human drugs
- Lead efforts to resolve issues raised in citizen petitions and develop detailed responses
- Advise on scope and applicability of the FD&C Act and other laws and regulations
- Handle all matters relating to information disclosure for CDER – policy and responses to disclosure requests under FOIA

Divisions of Regulatory Policy



- Divided into four divisions of regulatory policy for admin purposes
- Regulatory and Senior Regulatory Counsel – many with expertise in specific areas
- Expertise covers spectrum of policy issues in CDER

Information Disclosure Policy



- Our Division of Information Disclosure Policy handles all disclosure of CDER documents – policy and production
- Processes and responds to requests under the Freedom of Information Act (FOIA) for CDER documents
- Proactively reviews, redacts, and posts on FDA's website drug approval packages and CDER-issued warning letters
- Responds to requests for CDER documents made by external parties or court orders

Strategic Policy Council

- Facilitate coordination, management and oversight of CDER's policy
- Oversee priority setting and drive transparency during policy implementation
- Craft an overall CDER policy agenda
- Subcommittee: CDER Policy Council – regulations, guidance, and clearance

Exclusivity Board



- Provides oversight and recommendations for CDER exclusivity decisions (e.g., 5-year NCE; 3-year new clinical investigation)
- May work on CDER's policies and practices relating to exclusivity

Citizen Petitions



- Vehicle for stakeholder to ask FDA to take or not take or delay an administrative action (21 CFR 10.25; 10.30; 10.35)
- ORP leads the evaluation and response to Citizen Petitions for CDER
- Responses reflect FDA policy and constitute final agency action that can be challenged in Court
- Petitions and petition responses available at www.regulations.gov

Coordination Across FDA



- Work with other Centers and Commissioner's Office
 - Office of Policy: Implementing executive orders; external clearance
 - Office of Chief Counsel: Legal review of significant policy matters
 - Other Centers: cross-cutting policy

CDER RESPONSE TO COVID-19 PANDEMIC AND ORP's ROLE

COVID-19 Pandemic Response



- CDER response: all-hands on deck
- COVID-19 response required rapid policy development
 - Guidance development
 - Emergency use authorizations
 - Policy on regulatory flexibilities

Guidance Status

- Due to public health emergency, guidance document issued in final – docket for public comment
- Many guidances set to sunset after termination of public health emergency
- Certain guidance reflect Agency thinking relevant after termination and will be reissued in draft

Emergency Use Authorizations (EUA)



- Important tool in our fight against COVID-19
- Authority under section 564 to authorize the emergency use of unapproved products or unapproved uses of approved products if certain criteria are met
- Program offices and ORP (reg policy perspective) engaged in EUA requests and authorizations, revisions, or revocations

EUA Transparency

- CDER is committed to transparency around the EUA process – including our decisions to issue, revise, or revoke EUAs
- Last year, CDER announced plans, to the extent authorized by law, to post our scientific memos supporting the issuance, revision, or revocation of EUAs

EUA Memo Repository



- To ensure that our memos are easy to find and accessible, CDER has own page for its EUA memos
- You can find EUA reviews at <https://www.fda.gov/drugs/coronavirus-covid-19-drugs/cder-scientific-review-documents-supporting-emergency-use-authorizations-drug-and-biological>

Summary

- CDER has mechanisms to develop and coordinate policy across the Center and ORP plays a key role
- COVID-19 required rapid policy development with significant ORP involvement
- For information about this presentation, please contact stefanie.kraus@fda.hhs.gov

Challenge Question #1

ORP's work includes:

- A. Chairing the Strategic Policy Council
- B. Creating and supporting CDER policy initiatives
- C. Evaluating and responding to citizen petitions
- D. All of the above

Challenge Question #2

Which of the following statements is NOT true?

- A. ORP is significantly involved in CDER's COVID-19 pandemic response
- B. FDA has issued numerous guidance documents to assist our stakeholders during the COVID-19 pandemic
- C. Transparency is not an important part of the EUA process
- D. Information disclosure policy and processing disclosure requests are an important part of ORP's work

Questions?

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