U.S. FOOD & DRUG ADMINISTRATION

Communications in a Global Pandemic

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CDER | US FDA

Regulatory Education for Industry Annual (REdI) Conference – July 19, 2021

Learning Objectives

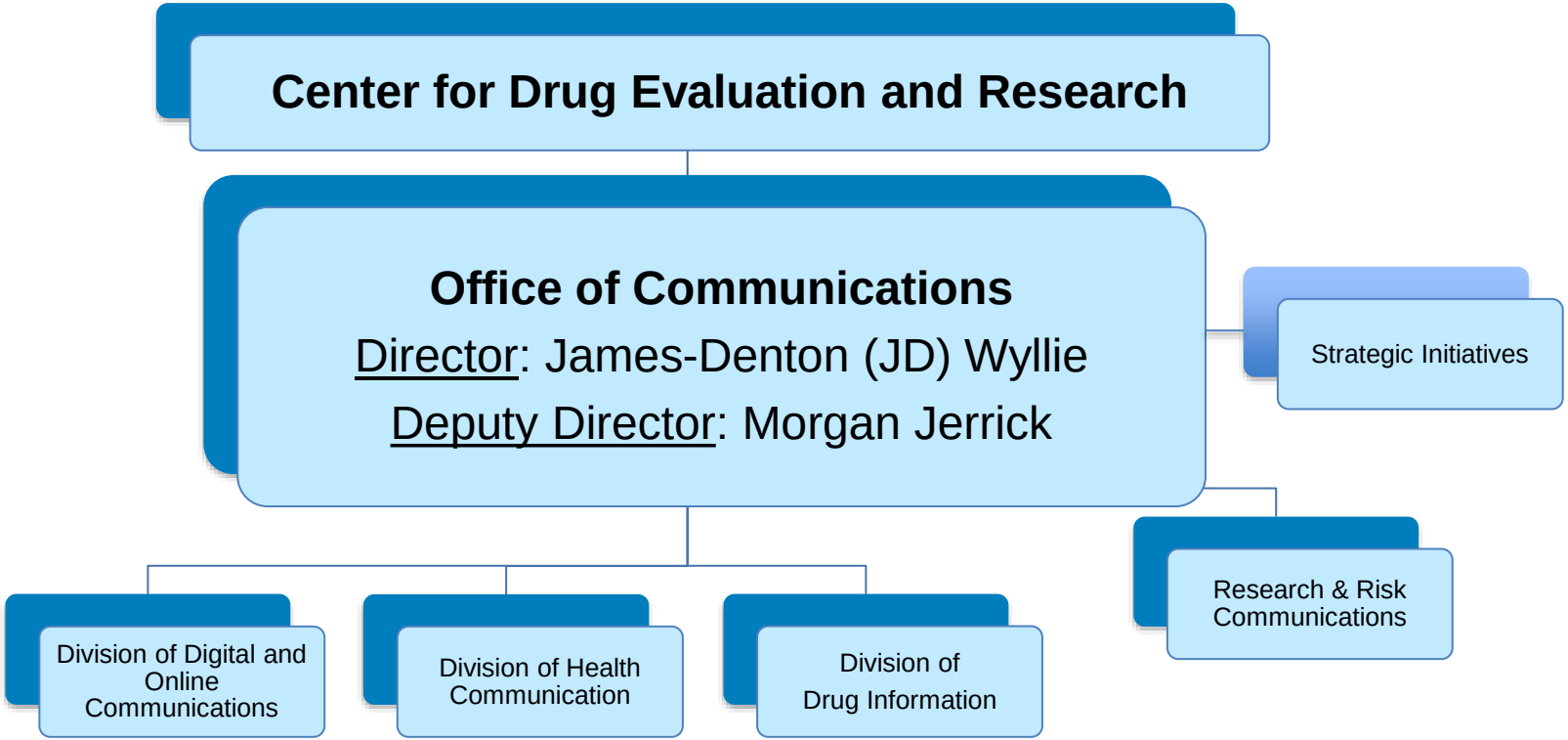
- Describe the OCOMM's commitment to transparency
- Outline our roles and responsibilities
- Highlight some of our contributions to public health

Overview

- Who We Are and What We Do
- Strategic Communication Goals
- Communication in Action
- Path Forward

Who We Are and What We Do

CDER | Office of Communications



What We Do

OCOMM's mission is to provide strategic communication and outreach related to and in support of the center's priorities and initiatives to protect public health.

Strategic Communication Goals

Strategic Communication Goals

1. Contribution to Public Good and Health
2. Building a Cohesive Communications Strategy
3. Demystifying Center Research and Processes
4. Maintaining Transparency/Building Trust

Communication in Action

Communication in Action

Contribution to Public Good and Health

Communication in Action

Contribution to Public Good and Health

FDA
450,156 followers
7mo

Today, we are reaffirming our commitment to transparency around the EUA process and sharing some updates on our plan to provide more information about FDA's decisions to issue, revise or revoke EUAs for drugs and biological products, including vaccines. https://bit.ly/2ILeEvl

LinkedIn

92 · 1 Comment

FDA Drug Information
@FDA_Drug_Info

Replying to @FDA_Drug_Info

Find important information about dosing instructions, potential side effects, and drug interactions in the fact sheets available here ⬇️

Emergency Use Authorization
Emergency Use Authorization (EUA) information, and list of all current EUAs
fda.gov

Twitter

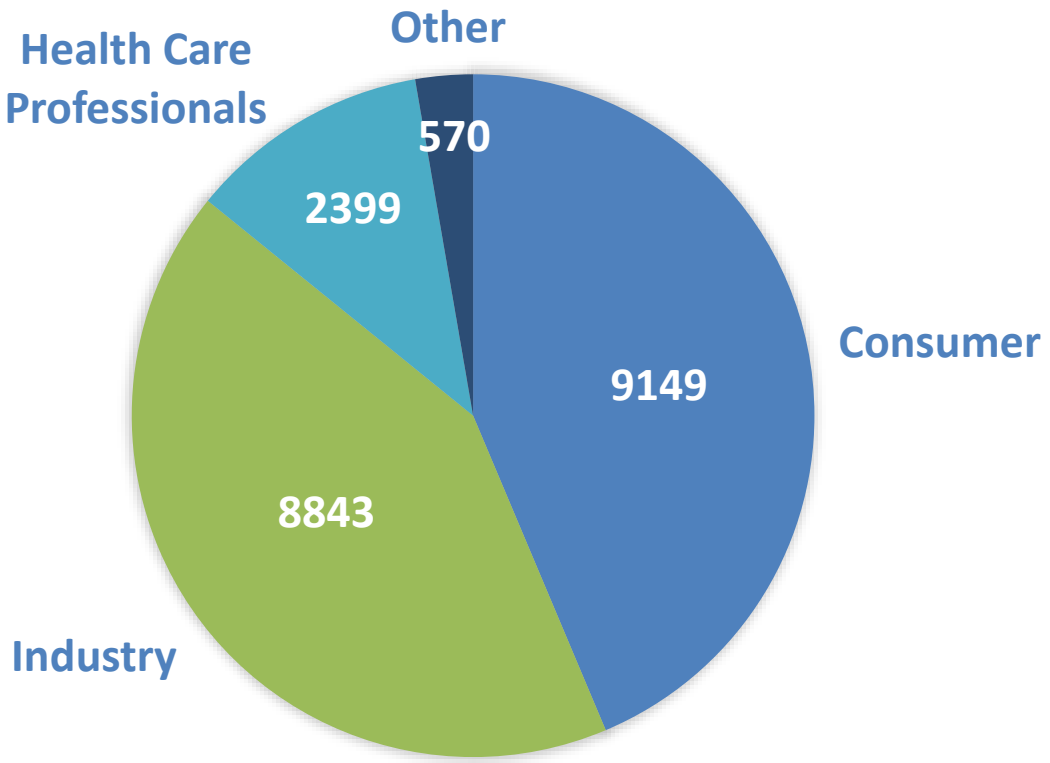
7:39 PM · Nov 21, 2020 · Twitter Web App

6 Retweets 19 Likes

Communication in Action

Contribution to Public Good and Health

DRUG-RELATED INQUIRIES
JANUARY 2020 - MARCH 2021



Communication in Action

Cohesive Communications Strategy

OCOMM served as:

- CDER's Joint Information Center (JIC) leads to coordinate review and clearance of drug-related messages for the Agency
- CDER's Communications representatives on COVID-19 Task Force Teams for sharing and escalating public concerns and sentiment
- JIC Web Team Lead for coordinating review and clearance for web content

Communication in Action

Cohesive Communications Strategy

- Identifying future communications opportunities and challenges
- Ensuring alignment with HHS and FDA messaging
- Collecting stakeholder feedback to inform comms and operational decision making
- Thoughtful engagement with external stakeholders on critical issues

Communication in Action

Cohesive Communications Strategy

Communication in Action

Demystifying Science and Center Processes

FDA Drug Information
@FDA_Drug_Info

Today, we updated our Coronavirus Treatment Acceleration Program (CTAP) webpage with new metrics and FAQs. As of July 31, 570+ drug development programs are in the planning stages & 270+ trials have been reviewed by FDA.

Coronavirus Treatment Acceleration Program (CTAP)
CTAP will use every available method to move new treatments to patients as quickly as possible
fda.gov

3:32 PM · Aug 7, 2020 · Twitter Web App

11 Retweets **9** Likes

FDA Drug Information
@FDA_Drug_Info

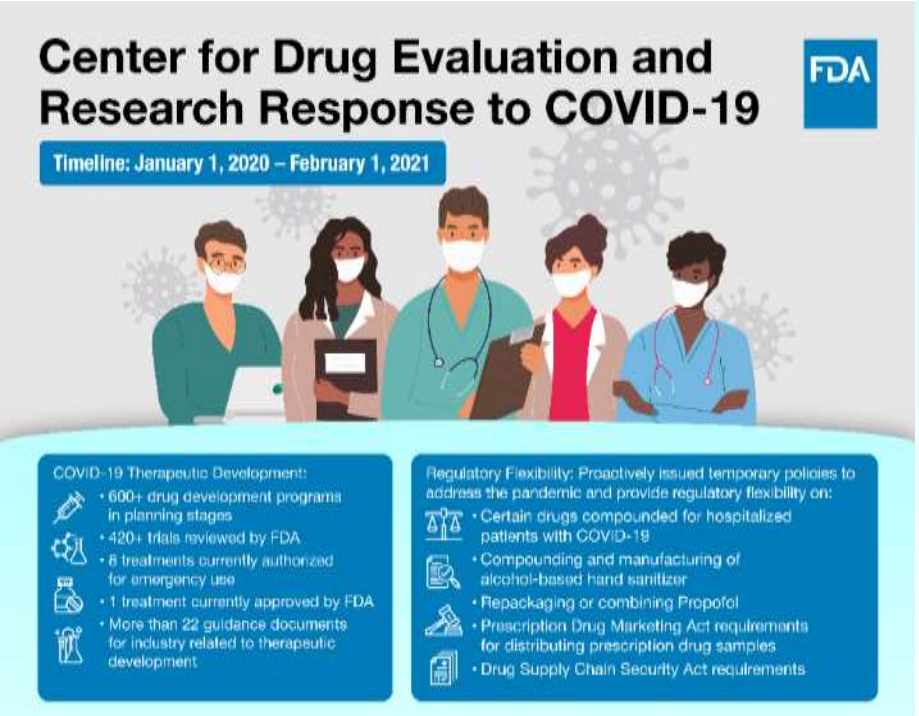
Learn how independent, in-depth analysis of data from 3 clinical trials supported FDA approval of Veklury (remdesivir) in the latest Spotlight on CDER Science: go.usa.gov/x77BV

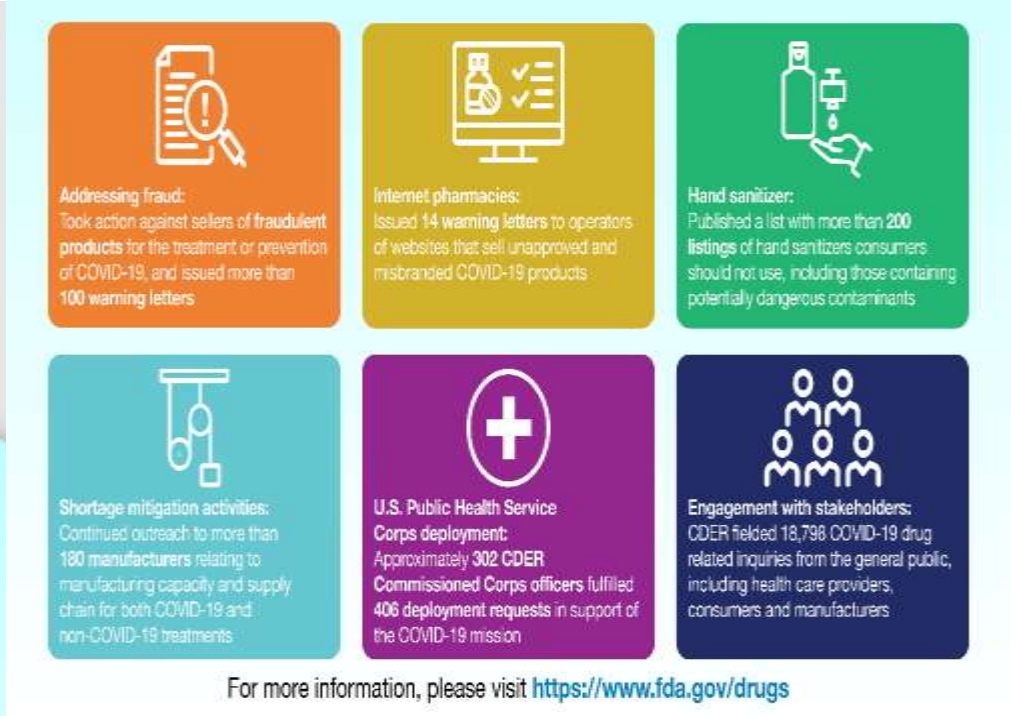
2:08 PM · Nov 25, 2020 · Twitter Web App

5 Retweets **6** Likes

Communication in Action

Demystifying Science and Center Processes





Communication in Action

Maintaining Transparency | Building Trust

CDER's Work to Meet User Fee Goals During the Pandemic

On January 31, 2020, the Secretary of Health and Human Services declared a public health emergency related to COVID-19, effective as of January 27, 2020. One of the challenges facing FDA during this public health emergency is how to ensure timely reviews of applications for drugs and biological products despite a worldwide pandemic and travel constraints, such as travel limitations, quarantine and social distancing requirements or lockdowns. America's patients depend on FDA to provide, when they meet our high scientific standards, approve medical products that are important to patients and health care professionals.

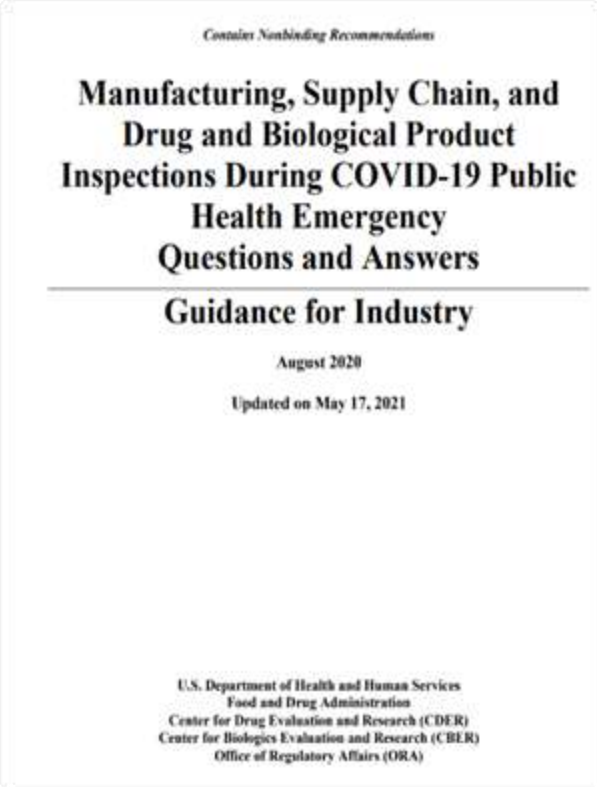
<u>Reduction in Pre-Approval Inspections Needed by Quarter:</u>

58% in FY2020 Q3

64% in FY2020 Q4

56% in FY2021 Q1

48% in FY2021 Q2



Contains Nonbinding Recommendations

Manufacturing, Supply Chain, and Drug and Biological Product Inspections During COVID-19 Public Health Emergency Questions and Answers

Guidance for Industry

August 2020

Updated on May 17, 2021

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Office of Regulatory Affairs (ORA)

Communication in Action

Maintaining Transparency | Building Trust

Posting review documents in a timely manner

EUA Action	Action Date	CDER Review Document
Original authorization	11/21/2020	CDER Review (3 MB)
Revised authorization	2/03/2021	CDER Review (136 KB)
Revised authorization	2/25/2021	CDER Memorandum (52 KB)
Updates to authorized labeling	3/18/2021	CDER Review (70 KB)
Updates to authorized labeling	5/14/2021	CDER Review (83 KB)

Communication in Action

Maintaining Transparency |Building Trust

FDA | CDER | Small Business and Industry Assistance

INDUSTRY NEWS

FDA In Brief: FDA Provides Guidance on Master Protocols for Evaluating Prevention, Treatment Options for COVID-19

The Small Business and Industry Assistance (SBIA) program in the Center for Drug Evaluation and Research provides guidance, education and updates for regulated industry.

Communication in Action

Outside of COVID-19 Pandemic

FDA
450,156 followers
9mo · Edited

Today, we published a study in JAMA Network Open that analyzes the quality of difficult-to-make pharmaceuticals marketed in the United States. The study found that all 252 drugs sampled met the U.S. market standards for uniformity and dissolution: https://lnkd.in/eKuzryD

This study provides a better understanding of the quality of prescription drugs in the U.S. by knowing that the tested samples met the U.S. market standards regardless of manufacturer or manufacturing region & brand or generic distinction.

85 · 3 Comments

FDA Drug Information @FDA_Drug_Info · May 5

Join us on May 7 at 1PM ET for a #CDERSBIA webinar to discuss the most common labeling mistakes found in generic drug application, how to avoid them, and other labeling tips!

Register: go.usa.gov/xHrNZ

1 6

Path Forward

Path Forward

Adjustments

- Consider the creative use of social media for more public messaging
- Promote FDA as one-stop shop for information
  - Whether it is a Fact Sheet or webpage, need a space where all information about a topic is placed (in a simple and engaging way)
- Meet with stakeholders when planning communications to ensure alignment
- Diagnose operational successes and failures

Path Forward

Areas for Improvement and Challenges

- Plain language communications for complex and regulatory concepts
- Combatting misinformation
- Using a variety of communication channels to reach niche audiences

Vision Statement

OCOMM's objective is to advance the scientific knowledge and understanding of the regulatory responsibility of the center to ensure the safety, effectiveness and quality of human drugs to various audiences.

Challenge Question #1

OCOMM's roles and responsibilities include all EXCEPT which of the following?

A. Escalation of issues via real-time feedback

B. Coordinate and centralize multi-center and agency level rollouts

C. IND Application review

D. Web communications

Challenge Question #2

JIC is an acronym for which of the following?

A. Joint Information Center

B. Joint Intelligence Committee

C. Joint Industry Council

D. Joint Implementation Commission

Closing Thought

In the Office of Communications, our top priority is ensuring that our communications play the role they are supposed to in the larger mission of FDA, to serve public health.

U.S. FOOD & DRUG
ADMINISTRATION