Knowing The Moment It Happens: CDER's Social Media Program

Roadmap for Engaging with the Center for Drug Evaluation and Research Public Workshop

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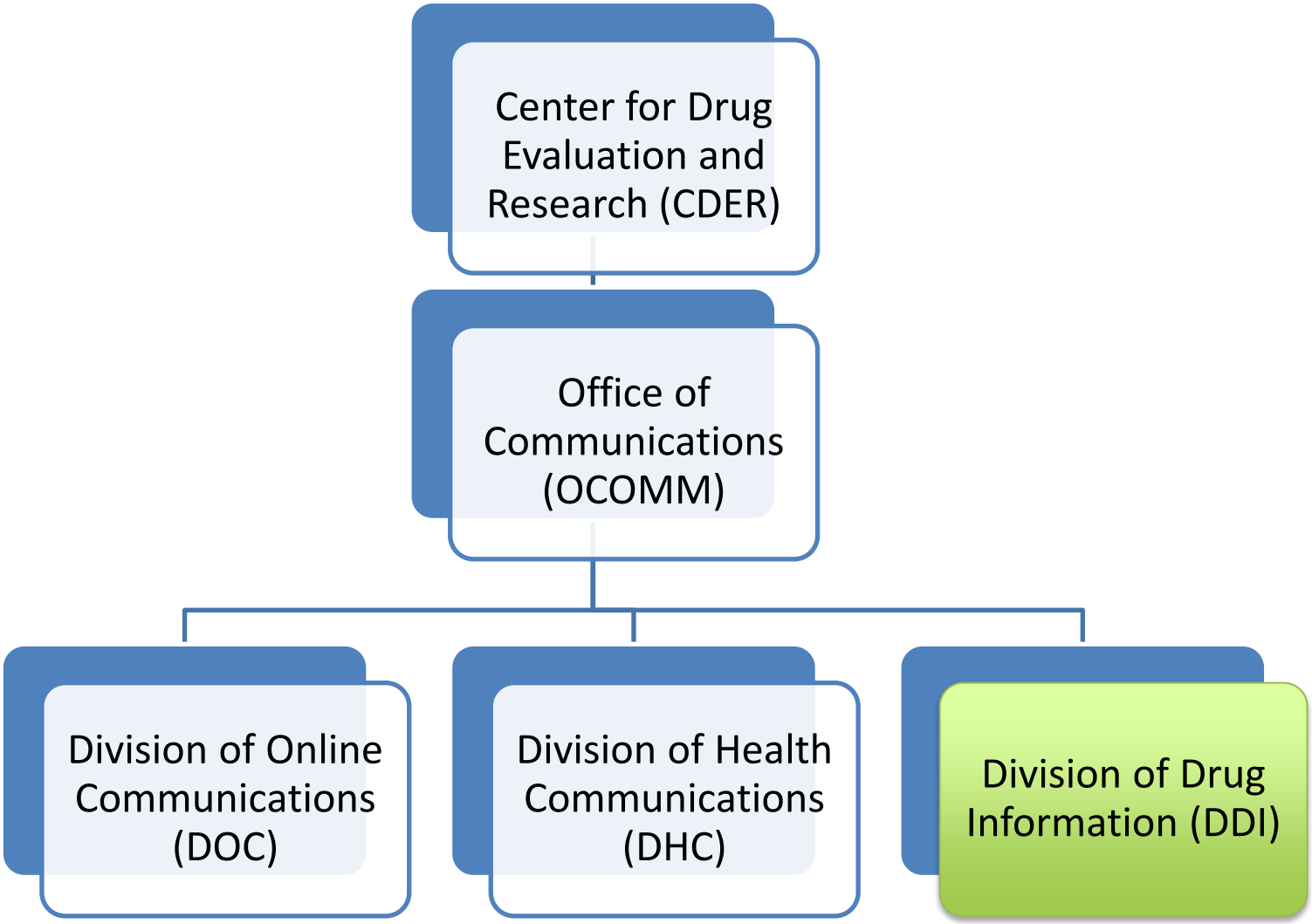

Center for Drug Evaluation and Research (CDER)
Office of Communications (OCOMM)
Division of Online Communications (DOC)
Division of Health Communications (DHC)
Division of Drug Information (DDI)

Division of Drug Information

- Focal point for public inquiries regarding human drug products and CDER initiatives
- Mission: optimize CDER's educational and communication efforts to our global community
- Build effective internal and external interactions to provide timely, accurate, and useful information through both traditional and social media channels
- Support the Agency's mission to promote and protect public health

www.fda.gov/aboutDDI

DISSEMINATING CDER COMMUNICATIONS

CDER's Social Media Platforms

Know The Moment It Happens

Twitter Handle: **@FDA_Drug_Info**

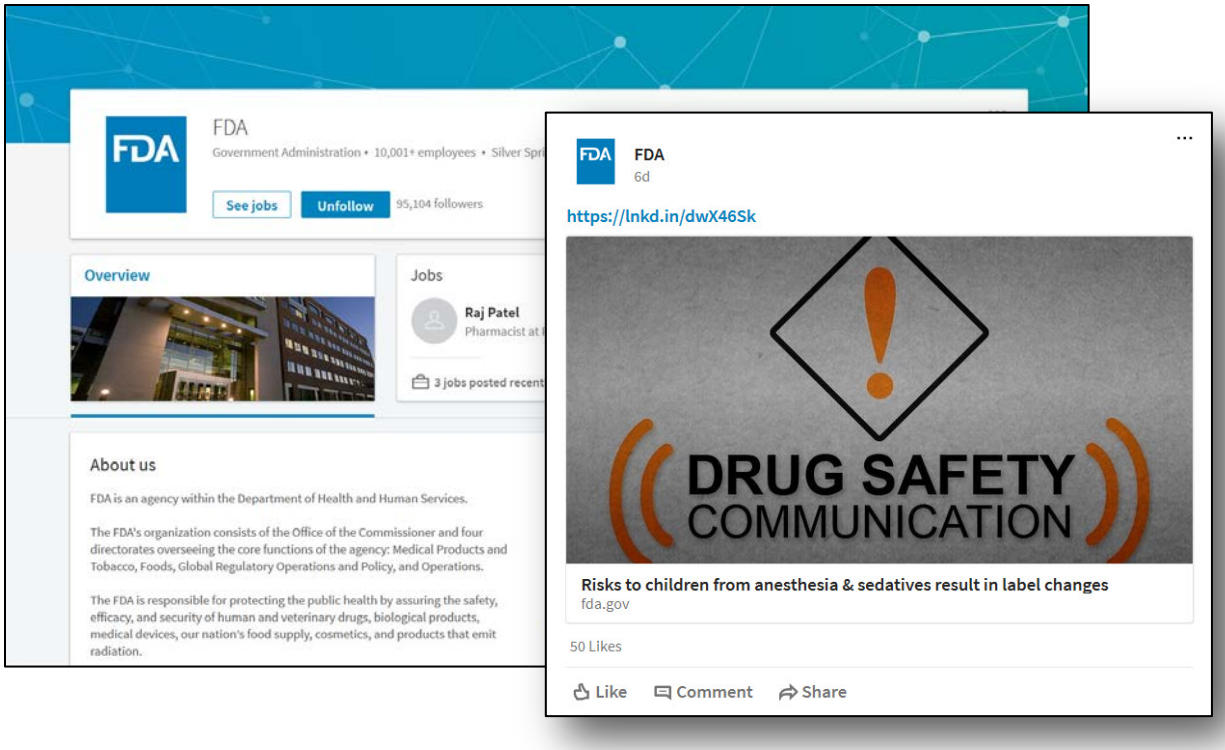
Know The Moment It Happens

Facebook: **U.S. Food and Drug Administration**

Know The Moment It Happens

Pinterest: **Drug Topics**

Know The Moment It Happens



LinkedIn Page: **U.S. Food and Drug Administration**

Know The Moment It Happens

FDA updates warnings for fluoroquinolone antibiotics-New Drug Safety Communication

Today FDA approved changes to the labels of fluoroquinolone antibacterial drugs for systemic use (i.e., taken by mouth or by injection). These medicines are associated with disabling and potentially permanent side effects of the tendons, muscles, joi... Show more

LinkedIn Group: **Global Alliance of Drug Information Specialists**

Know The Moment It Happens

The Division of Drug Information (DDI)- serving the public by providing information on human drug products and drug product regulation by FDA.

The U.S. Food and Drug Administration today approved Rydapt (midostaurin) for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) who have a specific genetic mutation called FLT3, in combination with chemotherapy. The drug is approved for use with a companion diagnostic, the LeukoStrat CDx FLT3 Mutation Assay, which is used to detect the FLT3 mutation in patients with AML.

Rydapt is a kinase inhibitor that works by blocking several enzymes that promote cell growth. If the FLT3 mutation is detected in blood or bone marrow samples using the LeukoStrat CDx FLT3 Mutation Assay, the patient may be eligible for treatment with Rydapt in combination with chemotherapy.

Common side effects of Rydapt in patients with AML include low levels of white blood cells with fever (febrile neutropenia), nausea, inflammation of the mucous membranes (mucositis), vomiting, headache, spots on the skin due to bleeding (petechiae), musculoskeletal pain, nosebleeds (epistaxis), device-related infection, high blood sugar (hyperglycemia) and upper respiratory tract infection. Rydapt should not be used in patients with hypersensitivity to midostaurin or other ingredients in Rydapt. Women who are pregnant or breastfeeding should not take Rydapt because it may cause harm to a developing fetus or a newborn baby. Patients who experience signs or symptoms of lung damage (pulmonary toxicity) should stop using Rydapt.

Rydapt was also approved today for adults with certain types of rare blood disorders (aggressive systemic mastocytosis, systemic mastocytosis with associated hematological neoplasm or mast cell leukemia). Common side effects of Rydapt in these patients include nausea, vomiting, diarrhea, swelling (edema), musculoskeletal pain, abdominal pain, fatigue, upper respiratory tract infection, constipation, fever, headache and shortness of breath.

For more information, please visit: Rydapt.

Listserv: **Drug Information Update**

Know The Moment It Happens

FDA restricts use of prescription codeine pain and cough medicines and tramadol pain medicines in children; recommends against use in breastfeeding women	April 20, 2017	Listen *Run Time: 00:3:00*	Transcript

Podcasts: **FDA Drug Safety Podcasts**

Podcast Available on iTunes

ReachMD
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FDA U.S. FOOD & DRUG ADMINISTRATION

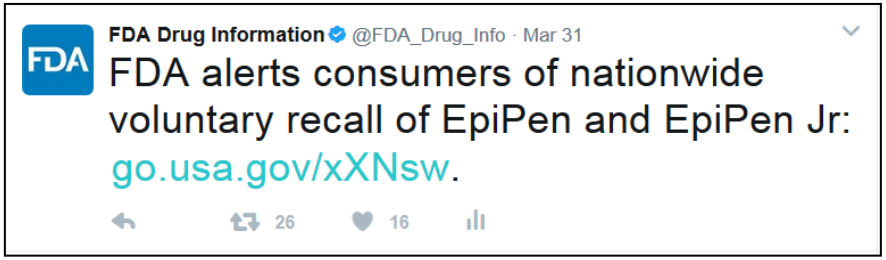
www.fda.gov/drugsafetypodcasts

What CDER Disseminates

- Drug Approvals
- Drug Safety Communications
- Drug Safety Alerts
- Meeting Announcements
- Tainted dietary supplements
- Health Campaigns
- …. and more!

ENGAGING ON SOCIAL MEDIA

EpiPen Example: Social Media Outreach



EpiPen Example

Will the firm issue refunds or replacements?

I need help with the recall process.

These are very expensive!

EpiPen Example

[redacted] You can buy epinephrine in a vial load the syringe for a lot less. https://www.valleyvet.com/swatches/1278RX_L_vvs_000.jpg

Like · Reply · Message · Remove Preview · April 2 at 9:39pm

U.S. Food and Drug Administration [redacted] according to the graphic, the product pictured is for animal use only. The Agency encourages patients to use FDA approved human drug products as these have been reviewed for safety and efficacy. FDA regulated products must also meet the Agency's high quality standards. Other FDA-approved epinephrine auto-injector products include Adrenaclick and Auvi-Q.

Like · Reply · 2 · Commented on by Kimberly Chiu [?] · April 3 at

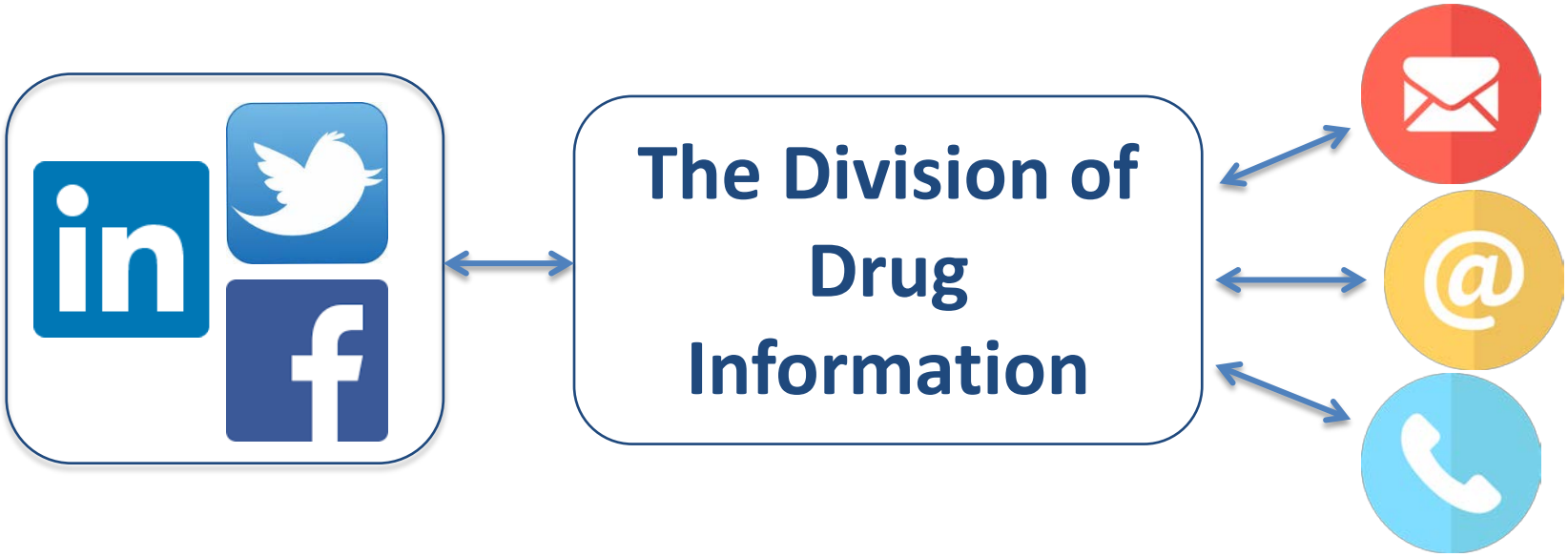
[redacted] And they are NOT replacing them free, just telling YOU to replace one...would that be at $600 as well?

Like · Reply · Message · 1 · April 1 at 3:20pm

U.S. Food and Drug Administration [redacted] please refer to Mylan's web page for product return and replacement instructions: www.mylan.com/EpiPenRecall. According to their web page, Mylan is committed to replacing recalled devices at no cost. Mylan also reassures patients that there will be no additional replacement-related financial burden to them as a result of this recall.

If you have additional questions or concerns, you may contact Mylan directly at 800-796-9526 or customer.service@mylan.com.

Listening and Responding



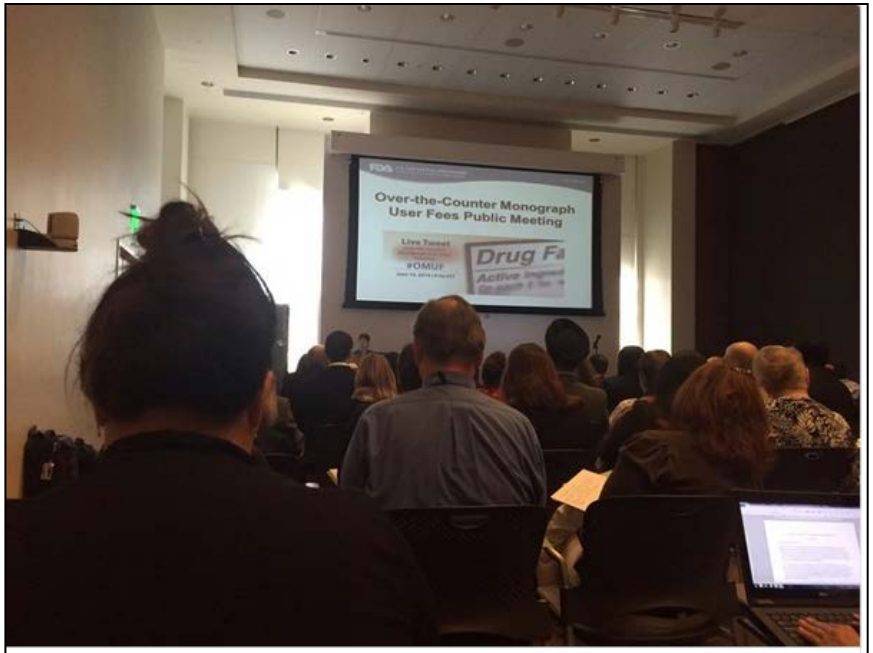
SOCIAL MEDIA EVENTS

Live Tweet


Live Tweet
Over-the-Counter
Monograph User Fees
Meeting
#OMUF
June 10, 2016 | 9-5p EST
Drug Fa
Active
FDA Drug Information
@FDA_Drug_Info
Follow
@FDA_Drug_Info will live tweet from the June 10th OTC Monograph User Fees Mtg: go.usa.gov/cS9FF. #OMUF
12:23 PM - 7 Jun 2016
8
7


FDA Drug Information
@FDA_Drug_Info
Follow
It's a packed room here at the #OMUF meeting. Are you in the room? Are you watching online? If so, let us know!
10:11 AM - 10 Jun 2016
5
6

Live Tweet



Cornell Stamoran
@stamoran
Follow

OTC Monograph User Fees? @US_FDA public hearing exploring need, approach. @PBOAssoc presents on Industry panel #OMUF

9:23 AM - 10 Jun 2016

2 2

PharmaMKT
@PharmaMKTnet

pharmaMKTnet McEnroe: #OMUF is tied to innovation which will jumpstart the monograph system while making sure products are safer. via FDA

10 MONTHS AGO

Santanu Mallik
@santanumallik
Follow

Retweeted FDA Drug Information (@FDA_Drug_Info):#OMUF Dr. Mahoney: The 1951 Durham-Humphrey Amendment created 2... fb.me/78MLuBqlX

12:25 PM - 10 Jun 2016

Twitter Chats

FDA Drug Information @FDA_Drug_Info · 26 Oct 2016

Join us on TMRW at 2p ET to talk about safe medication use during pregnancy & other tips for healthy pregnancy. Use #FDApregnancychat.

1 19 12

FDAWomen @FDAWomen · 27 Oct 2016

Q1: Let's get started. Why is it so important for us to discuss medication use during pregnancy? #FDApregnancychat

5 8

FDA Drug Information @FDA_Drug_Info · 27 Oct 2016

A1: Not all medicines are safe to take when pregnant- some can harm you and your baby. #FDApregnancychat

22 13

Questions?

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Raj.Patel@fda.hhs.gov

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