U.S. FOOD & DRUG ADMINISTRATION

The Brief Summary

FDA | CDER | Office of Prescription Drug Promotion

NEWSLETTER

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Gray Matters

We're big fans of Premier League football here in OPDP (even if we *don't* all follow the palace). And with the recent finales of the regular season, several prime tournaments, and Ted Lasso, it seems like a good time to reflect on teamwork.

Our two review divisions, Division of Advertising and Promotion I and II (DAPR I and II) are structured into teams by therapeutic areas. Within the Division of Promotion Policy, Research and Operations (DPPRO, our newest division), we have four teams: Health Science Policy Analysts, Regulatory Counsels, Social Scientists and Project Managers. As you might expect, we regularly work across teams within OPDP – Reviewers join Policy Analysts on guidance development workgroups, the Social Scientists consult on advisory reviews and compliance actions, and of course we all seek legal analysis and direction from our Regulatory Counsels.

But we don't limit our teamwork to the boundaries of OPDP. We frequently consult and collaborate with our colleagues, for example, in the Office of New Drugs and the Oncology Center of Excellence regarding labeling specifics, statistical analyses and data considerations . Their perspectives significantly contribute to our

understanding and evaluation of promotional claims. OPDPers also serve on superoffice-, center-, and even agency-wide working groups as subject matter experts or project leads.

This multi-disciplinary teamwork brings a fuller perspective to consideration of issues, helps ensure consistency across decisions, and builds interpersonal networks that enable further collaboration. As the agency grows, and with the challenges of a hybrid workforce, these relationships and the ability to create and join effective teams is even more important.

As I've mentioned before, many OPDPers will tell you they joined the office to be part of something bigger than themselves. Many of our FDA colleagues will say the same thing. Like AFC Richmond, we believe. If you'd like to join our great team, you can find FDA opportunities on USAJOBS.gov and on the Agency's LinkedIn page.

Best,

kbg

Recorlev Untitled Letter:

On June 7, 2023, OPDP issued an Untitled Letter (UL) to Xeris Pharmaceuticals, Inc. regarding the company's product Recorlev (levoketoconazole) tablets. The UL is posted on the OPDP Untitled Letters 2023 webpage. A copy of the UL can be downloaded at this link.

Federal Register Notices:

30-day notices for information collections:

- "Perceptions of Prescription Drug Products with Medication Tracking Capabilities." The Federal Register Notice can be viewed and downloaded here.
- "Tradeoff Analysis of Prescription Drug Product Claims in Direct-to-Consumer and Healthcare Provider Promotion." The Federal Register Notice can be viewed and downloaded here.
- "Endorser Status and Actual Use in Direct-to-Consumer Television Ads." The Federal Register Notice can be viewed and downloaded here.

60-day notices for information collection:

- "A Survey on Quantitative Claims in Direct-to-Consumer Prescription Drug Advertising." The Federal Register Notice can be viewed and downloaded here.

Publications:

The Social Science team published two new manuscripts:

- Patient understanding of oncology clinical trial endpoints in direct-to-consumer television advertising
- Complexity of data displays in prescription drug advertisements for healthcare providers

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ICYMI

On June 27, 2023, the FDA issued a final guidance for industry entitled "Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer (DTC) Promotional Labeling and Advertisements." This guidance finalizes the draft guidance issued in October 2018. The guidance provides recommendations for presenting quantitative efficacy and risk information in DTC promotional labeling and advertisements for prescription human drug and biological products, prescription animal drugs, and in DTC promotional labeling for nonprescription animal drugs (collectively, "promotional communications"). The recommendations are informed by current research findings related to communicating health information and cover the following topics:

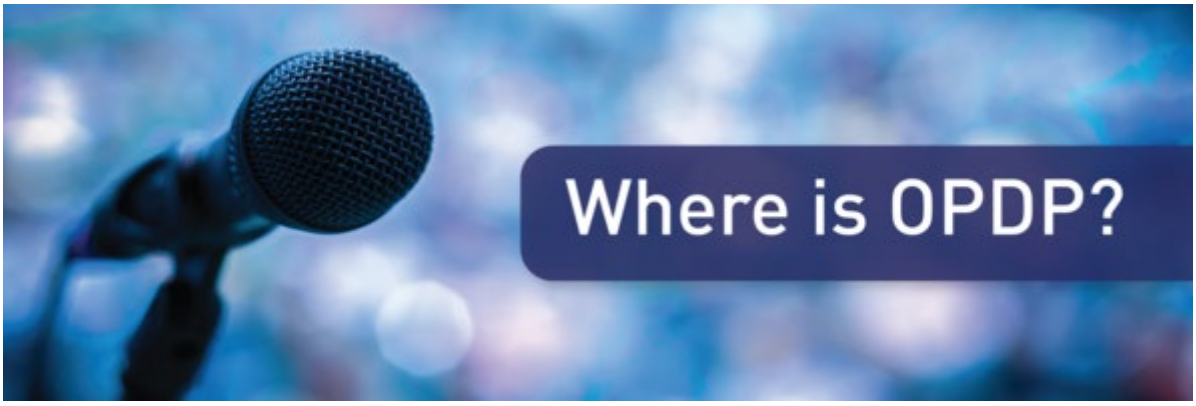
- Providing quantitative efficacy or risk information from the control group, when applicable;
- Presenting probability information in terms of absolute frequencies, percentages, and relative frequencies;
- Formatting quantitative efficacy or risk information; and
- Using visual aids to illustrate quantitative efficacy or risk information.

The guidance outlines recommendations for how manufacturers, distributors, and packers (collectively, "firms") that include quantitative efficacy or risk information in DTC

promotional communications for their drugs can make the language and presentation more consumer-friendly.

Focus on Research

The latest issue of the CDER Regulatory Science newsletter, a compendium of news updates about regulatory science activities in CDER, highlights research from OPDP's own Helen Sullivan and Amie O'Donoghue. This new spotlight, "The Role of Disclosures: Helping to Understand Oncology Clinical Trial Endpoints" discusses recent FDA research focusing on the role of disclosures in helping consumers understand oncology endpoints in direct-to-consumer television advertisements. The findings show research participants have some difficulty in differentiating progression-free survival and overall response rate from overall survival on drug advertisements without a disclosure that the therapy 'has not yet been shown to extend life.' These findings demonstrate that people may be overly optimistic when they see ads with claims about overall response rate and progression-free survival without a disclosure. Read all about the study here.



OPDP Social Scientist Kevin Betts presented a poster at the FDA Science Forum on his study of consumer and primary care physicians' understanding of terms and phrases commonly used in prescription drug promotion. The FDA Science Forum is held biennially to inform the public about the groundbreaking science conducted at the Agency, and to show how scientific research is used in FDA's regulatory decisions to protect and promote public health. The theme for this year's forum was Advancing Regulatory Science Through Innovation. The forum highlighted many areas of FDA research and was open to the public, industry, academia, patient advocates, government agencies, and current and potential collaborators.

Katie Gray presented OPDP updates at the Pharmaceutical Compliance Congress Annual Conference in April. The address included comments on compliance actions, policy updates, and OPDP newsy notes.

The Office of Prescription Drug Promotion (OPDP) resides in the Office of Medical Policy (OMP) in the Center for Drug Evaluation and Research (CDER).

OPDP Contacts

OPDP RPM Mailbox: CDER-OPDP-RPM@fda.hhs.gov

OPDP eCTD Mailbox: OPDPeCTD@fda.hhs.gov

Bad Ad Mailbox: BadAd@fda.gov

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