The Brief Summary

FDA | CDER | Office of Prescription Drug Promotion

NEWSLETTER

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Office Director
Dr. Catherine (Katie) Gray

Gray Matters

My kids headed back to school recently, and I again tackled the annual back-to-school task list. My personal cheat sheet and the number of pre-populated (but not dated) forms increase every fall, with the hopes of increased efficiency the next year. This year's effort made me think of an OPDP "must haves" kit. Instead of pencils, notebooks, a pre-populated emergency contact form, and a backpack, here's some resources to help you keep up with OPDP's activities and hopefully increase your efficiency.

First and foremost, there is a lot of information on our website. We update it regularly – please also see the piece about the newest Bad Ad update later in this issue. I have the Regulatory Information page bookmarked; it's a one-stop-shop for our statute, regulations and guidance documents. You can also find information on compliance actions (Warning Letters and Untitled Letters) at the bottom of the page.

The Federal Register publishes daily, and the table of contents can be found here. This is where you will find any OPDP rules, notice of availability for our guidances, and 60-day and 30-day notices for our research studies.

The Unified Agenda, also known as the Semiannual Regulatory Agenda, is published twice a year in the spring and fall in the Federal Register. It describes regulatory actions agencies are developing or have recently completed. You can view the Unified Agenda for FDA here.

The CDER guidance agenda lists new and revised draft guidance documents planned for publication in a given year. You can find the agenda at the bottom of this page.

And of course, make sure you are subscribed to The Brief Summary if you aren't already! We also use the newsletter mailing list for special announcements, so it's extra important that you subscribe.

Wishing you a successful year of learning and growth!

Best,

kbg

On August 4, 2023, OPDP issued a Warning Letter (WL) to AstraZeneca Pharmaceuticals LP regarding the company's product Breztri Aerosphere (budesonide, glycopyrrolate, and formoterol fumarate) inhalation aerosol. The WL is posted on the FDA Warning Letter webpage. A copy of the WL can be found here.

On August 11, 2023, OPDP issued an Untitled Letter (UL) to Exeltis USA Inc. regarding the company's product Slynd (drospirenone) tablets. The UL is posted on the OPDP Untitled Letters 2023 webpage. A copy of the UL can be downloaded at this link.

On September 14th, Duke-Margolis in collaboration with OPDP, hosted a public meeting on *The Future of Prescription Drug Promotion and Digital Marketing*. The meeting included four panels that discussed the current state of digital marketing and the future of emerging technologies and platforms. The meeting agenda and materials are available at this webpage: The Future of Prescription Drug Promotion and Digital Marketing (duke.edu). Check out the upcoming January issue for a meeting summary and more on digital marketing!

Staff Spotlight

Jennifer Chen, Reviewer

Jennifer earned her Pharm.D. from Purdue University in 2019. Prior to joining FDA, she earned an MBA while completing a two-year regulatory pharmaceutical fellowship with rotations working in the pharmaceutical industry, FDA OPDP, and Purdue University. In her free time, she enjoys baking, listening to audiobooks, and doing home exercises.

Jennifer joined OPDP as a reviewer in July 2021, and she initially worked with solid tumor oncology products, followed by hematology oncology products. Currently, she serves as a reviewer on a team that provides support to the OPDP promotional review divisions, with a focus on high-priority reviews and special projects. As a pharmacist, she enjoys having an impact on how pharmaceutical companies communicate with patients and healthcare providers through drug promotion. She initially gained experience working in OPDP as a regulatory pharmaceutical fellow in 2020. After completion of her fellowship program, she chose to pursue a career at OPDP because her fellowship experience in the office was meaningful and rewarding. She enjoys working with the kind and supportive team at OPDP.

OPDP Social Science Web Updates

The OPDP Social Science Research webpage was updated in September 2023. The following updates were made to each webpage:

Completed Research Projects

- 3 new entries and corresponding publications have been added:
    - Data Displays in Professional Promotion
        - Complexity of Data Displays in Prescription Drug Advertisements for Healthcare Providers
        - Healthcare Providers' Understanding of Data Displays of Clinical Trial Information: A Scoping Review of the Literature
    - Study of Oncology Indications in Direct-to-Consumer Television Advertising
        - Patients' Understanding of Oncology Clinical Endpoints: A Literature Review

        - Patients' Understanding of Oncology Clinical Endpoints: Environmental Scan and Focus Groups
        - Patient Understanding of Oncology Clinical Trial Endpoints in Direct-to-Consumer Television Advertising
    - Assessment of Terms and Phrases Commonly Used in Prescription Drug Promotion

- The new entries bring the total number of completed research projects to 53.

Research Pending Peer Review and Publication

- One project was moved from this webpage to the Completed Research Projects webpage:
    - Study of Oncology Indications in Direct-to-Consumer Television Advertising
- 4 new entries have been added:
    - Empirical Study of Promotional Implications of Proprietary Prescription Drug Names
    - Endorser Status and Explicitness of Payment in Direct-to-Consumer Promotion
    - Physician Interpretation of Information About Prescription Drugs in Scientific Publications vs. Promotional Pieces
    - Study of Multiple Indications in Direct-to-Consumer Television Advertisements
- There are now 6 projects Pending Peer Review and Publication.

Research in Progress

- One project was moved from this webpage to the Completed Research Projects webpage:
    - Assessment of Terms and Phrases Commonly Used in Prescription Drug Promotion
- 4 projects were moved from this webpage to the Research Pending Peer Review and Publication webpage:
    - Empirical Study of Promotional Implications of Proprietary Prescription Drug Names
    - Endorser Status and Explicitness of Payment in Direct-to-Consumer Promotion
    - Physician Interpretation of Information About Prescription Drugs in Scientific Publications vs. Promotional Pieces

    - Study of Multiple Indications in Direct-to-Consumer Television Advertisements

- 6 new entries have been added:
    - Adherence Potential and Patient Preference in Prescription Drug Promotion
    - Dosage Form Presentations in Direct-to-Consumer Prescription Drug Television Advertisements
    - Endorser Status and Actual Use in Direct-to-Consumer Television Ads
    - Perceptions of Prescription Drug Products with Medication Tracking Capabilities
    - Prescription Drug Promotion: State of the Literature and Consumer/HCP Perspectives on Emerging Topics
    - A Survey on Quantitative Claims in Direct-to-Consumer Prescription Drug Advertising
- There are now 14 research projects actively in progress.

Recent OPDP Publications

The Social Science team published a new manuscript:

- A Scoping Review of Empirical Research on Prescription Drug Promotion[1]

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[1] Aikin, KJ, Sullivan, HW, Caporaso, A, et al. Attention to risk information in direct-to-consumer prescription drug print ads: An eye-tracking study. Pharmacoepidemiol Drug Saf. 2022; 1- 9.

[2] Helen W. Sullivan, Amie O'Donoghue, Shane Mannis, Amanda M. Carpenter, Character-space-limited online prescription drug communications: Four experimental studies, Research in Social and Administrative Pharmacy, 2022, in press

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Focus on Policy

Five Out of Four People Admit They're Bad at Fractions – read on for recommendations on how you can help audiences understand quantitative efficacy and risk information in prescription drug promotion!

On June 27, 2023, 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. Information that numerically addresses the likelihood or magnitude of a drug's efficacy or

risks – known for the purposes of this guidance as quantitative efficacy and risk information – is often used in promotional communications. When firms develop DTC promotional communications, they should consider how to best convey information about a drug's efficacy and risks, so the audience understands the information. This includes consideration of whether to provide efficacy and risk information by using words, numbers, or visual aids, or a combination of these elements.

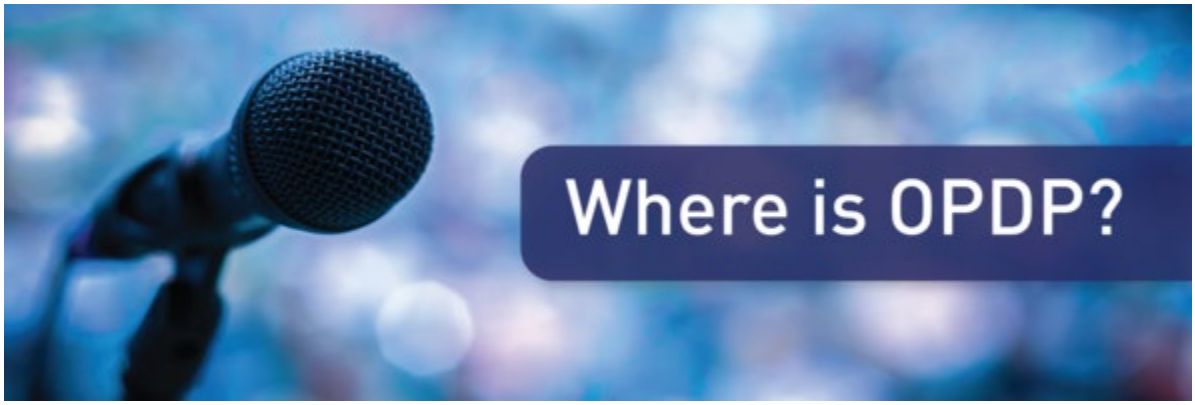
FDA's final guidance "Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer (DTC) Promotional Labeling and Advertisements" covers the following topics:

- 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.

100% of OPDP employees recommend clicking HERE and reading the full guidance to learn more!

OPDP's Bad Ad Program

The Bad Ad program continues its outreach to help healthcare providers recognize and report potentially false or misleading prescription drug promotion. New materials including an infographic and short video have been created to help spread the word about the program. Learn more and access these materials on the Bad Ad website. As a reminder, you can report potentially false or misleading prescription drug promotion by emailing BadAd@fda.gov or calling 855-RX-BADAD or 855-792-2323.



DIA will host a roundtable webinar on October 18th to present best practices and recommendations when marketing prescription drug products through Responsive Search Ads (RSA). The roundtable panel will include representatives from Industry and will be moderated by Jason Cober from OPDP. Panelists will discuss their approach to publishing Responsive Search Ads,

considerations when developing and publishing through RSA, and best practices and recommendations. The webinar is free and open to the public. Registration is open on the DIA website: https://www.diaglobal.org/en/course-listing/webinar/2023/10/responsive-search-ads-rsa-and-prescription-drug-promotion.

The Food and Drug Law Institute (FDLI) will be holding its annual "Advertising & Promotion for Medical Products Conference" November 2nd and 3rd. OPDP's Katie Gray will present Updates in Advertising & Promotion: FDA Insights, and Helen Sullivan and Amy Muhlberg will participate in a panel on Regulatory Updates Concerning Direct-to-Consumer Communication. The preliminary agenda is available here: https://www.fdli.org/2023/08/2023-advertising-and-promotion-conference-agenda/

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

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OPDP Homepage

Previous Editions of *The Brief Summary* are available on the OPDP News webpage

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