The Brief Summary

FDA | CDER | Office of Prescription Drug Promotion

NEWSLETTER

IN THIS EDITION

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Gray Matters

I often get the question, "When is OPDP's busy season?" *Always*. This issue of *TBS* validates that answer. With the constant activity, it's hard to believe that one year ago we were wrapping up work on the Direct-to-Consumer Prescription Drug Advertisements: Presentation of the Major Statement in a Clear, Conspicuous, and Neutral Manner in Advertisements in Television and Radio Format (aka CCN) Final Rule. We were dotting i's, crossing t's, checking footnotes, and anxiously awaiting a publication date. As we've discussed in this newsletter before, the rule was published on November 21st, 2023. It became effective May 20th, 2024. And instead of ruining another holiday, we're splitting the distance between Veteran's Day and Thanksgiving with a November 20th, 2024, compliance date. What does November 20th mean for regulated industry? It means that you must bring all DTC TV/radio ads subject to the CCN standards into compliance by that date. Of course, we recommend

ensuring ads are brought into compliance as soon as possible!

What about voluntary requests for comments from OPDP? Since the May 20th effective date, we have been receiving and reviewing draft DTC ads in TV/radio format for compliance with the CCN final rule and providing comments and recommendations, as appropriate. That won't change after November 20th. What will change is that OPDP will consider a compliance letter for non-compliant ads.

We issued the rule to help ensure that risk information is presented in a way that helps consumers notice, attend to, and understand the drug's risks, as well as to fulfill a Congressional directive. As the compliance date nears, I want to thank the many current and former OPDP staff who worked on this project. It is exciting to see all that effort come to fruition.

Finally, we have some new resources since the last time we talked about CCN. On June 26, 2024, OPDP presented a Small Business Industry Assistance webinar on this topic. A recording of the webinar and associated resources are freely available to the public. Please also visit our webpage for updates.

Happy Fall!

Best,

kbg

July 8th, 2024, FDA issued a draft guidance for industry entitled, "Addressing Misinformation About Medical Devices and Prescription Drugs: Questions and Answers," which, when finalized, will describe the agency's current thinking on common questions companies may have when voluntarily addressing misinformation about or related to their approved/cleared medical products.

This revised draft guidance would apply only to approved/cleared medical products, which include medical devices for human use (including biological products), prescription human drugs (including biological products), and prescription animal drugs.

This document revises and replaces the previous draft guidance for industry entitled "Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices," issued in June 2014.

This revised guidance will help members of the public get the accurate, up-to-date, science-based information they need to inform their decisions about medical products to maintain and improve their health.

You can read Commissioner Califf's remarks on the guidance here.

On July 17, 2024, OPDP issued an Untitled Letter (UL) to Kaleo, Inc. regarding the company's product Auvi-Q (epinephrine injection, USP) for intramuscular or subcutaneous use. The UL is posted on the OPDP Untitled Letters webpage.

On August 1, 2024, OPDP issued an Untitled Letter (UL) to Mirati Therapeutics Inc., a Bristol Myers Squibb Co., regarding the company's product Krazati (adagrasib) tablets. The UL is posted on the OPDP Untitled Letters webpage.

On August 29, 2024, OPDP issued an Untitled Letter (UL) to AbbVie, Inc., regarding the company's product Ubrelvy (ubrogepant) tablets. The UL is posted on the OPDP Untitled Letters webpage.

On September 24, 2024, OPDP's Sola Adejuwon provided an update on the Bad Ad program through FDA's Division of Drug Information's CE Webinars. You can learn more about the program at the FDA Drug Topics Webinar website.

Federal Register Notices

On August 8, 2024, FDA announced a 60-day notice for an information collection titled “Healthcare Provider Survey of Topics Related to Prescription Drug Promotion.” Either electronic or written comments on the collection of information must be submitted by October 7, 2024. The Federal Register Notice can be downloaded here.

Focus on Research

A recent Spotlight on CDER Science highlighted research from OPDP’s own Kevin Betts and Kathryn (Kit) Aikin. The July feature, “Disease Awareness and Prescription Drug Communications on Television: Evidence for Conflation and Misleading Product Impressions,” discusses recent FDA research into how the similarity, proximity, and frequency of exposure to a disease awareness communication and a prescription drug television advertisement impact consumer perception and understanding of the benefits and risks of a prescription drug. The findings demonstrate the potential for disease awareness communications and prescription drug ads on TV to confuse consumers regarding the benefits and risks of a drug. This work advances CDER research on how advertising features, such as graphics, format, and disease and product characteristics, impact the communication and understanding of prescription drug risks and benefits. You can read more about the studies here.

OPDP Website Refresh

Last month, we updated several OPDP websites to make it easier for visitors to find information. Many of the site improvements are in response to feedback and frequently asked questions that we received from visitors.

OPDP Homepage

We updated the OPDP homepage to improve the prominence and organization of the underlying OPDP webpages.

- All webpage links on the OPDP homepage are now accompanied by an icon and a brief description of the content on the linked page.

- We added links for OPDP Warning Letters and OPDP Untitled Letters to the OPDP Homepage.
- We removed the “Announcements” section of the OPDP Homepage.
    - Going forward, all OPDP announcements will be posted on the OPDP News webpage. We will also send announcements to the OPDP listserv whenever a new item is added to the OPDP News webpage. You can sign up for the OPDP listserv here.
    - You can find all previous announcements since 2021 displayed on the OPDP News webpage.

- We expanded the “What We Do” section of the OPDP homepage to include descriptions of all OPDP staff roles.

Bad Ad Program

We refreshed the Bad Ad Program webpage to include instructions for visitors seeking information on how to report potentially false or misleading information to OPDP.

- We moved the Bad Ad Program overview video to the top of the page to make it more prominent and easier to find.
- Under the “Reporting” section, we added new instructions for submitting reports. The instructions include suggestions for report submitters to consider when submitting a report to the Bad Ad Program. While this suggested information is not required, it can help OPDP staff route incoming reports more efficiently.
- We added a list of FDA contacts to the “Reporting” section as a guide for visitors who wish to report on areas outside of prescription drug promotion.

OPDP Metrics

We revised the charts on the OPDP Metrics webpage to display information more efficiently. The charts now include data labels which display the metric counts and the data tables which were previously displayed below the charts have been removed.

Social Science Research

The OPDP Social Science Research webpage was also updated in September, 2024. The following updates were made to each webpage:

- Completed Research Projects

    - Four entries and corresponding publications have been added:
        - Disease Awareness and Prescription Drug Promotion on Television
        - Physician Interpretation of Information About Prescription Drugs in Scientific Publications vs. Promotional Pieces
        - Prescription Drug Promotion: State of the Literature and Consumer/HCP Perspectives on Emerging Topics

        - Study of Disclosures to Health Care Providers Regarding Data That Do Not Support Unapproved Use of an Approved Prescription Drug

    - These entries bring the total number of completed research projects to 57.

- Research Pending Peer Review and Publication

    - Two projects were moved from this webpage to the Completed Research Projects webpage:
        - Disease Awareness and Prescription Drug Promotion on Television
        - Physician Interpretation of Information About Prescription Drugs in Scientific Publications vs. Promotional Pieces

    - Five entries have been added:
        - Examination of Secondary Claim Disclosures and Biosimilar Disclosures in Prescription Drug Promotional Materials
        - Experimental Study of an Accelerated Approval Disclosure
        - Medical Conference Attendees' Observations about Prescription Drug Promotion
        - Perceptions of Prescription Drug Products with Medication Tracking Capabilities
        - Text Analysis of Proprietary Drug Name Interpretations

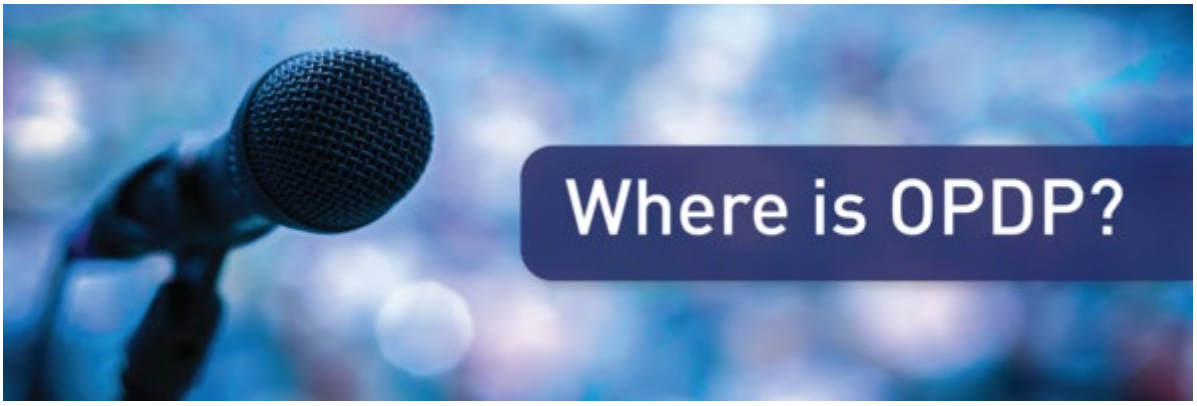
    - There are now 9 projects pending peer review and publication.

- Research in Progress

    - Two projects were moved from this webpage to the Completed Research Projects webpage:
        - Prescription Drug Promotion: State of the Literature and Consumer/HCP Perspectives on Emerging Topics
        - Study of Disclosures to Health Care Providers Regarding Data That Do Not Support Unapproved Use of an Approved Prescription Drug

    - Five projects were moved from this webpage to the Research Pending Peer Review and Publication webpage (see 'added' entry in that section)
    - Two new entries have been added:
        - Examination of Implied Claims in Direct-to-Consumer Prescription Drug Promotion
        - Healthcare Provider Survey of Topics Related to Prescription Drug Promotion

- There are now nine research projects actively in progress.



OPDP Office Director Catherine (Katie) Gray will present at the FDLI Advertising and Promotion for Medical Products Conference on October 17, 2024, and the Annual Pharma and Medical Device Ethics and Compliance Congress on October 28, 2024.

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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