# The Brief Summary

FDA | CDER | Office of Prescription Drug Promotion

NEWSLETTER

Office Director
Dr. Catherine (Katie) Gray

## Gray Matters

Happy New Year! I had big plans to make January's issue of The Brief Summary about all things digital marketing. However, so much else has happened in the last three months that I must reluctantly postpone the digital marketing focus for a future issue.

This issue includes our usual January metrics roundup – it's always fascinating to try and spot trends so we can try to get ahead of things. We also like to be transparent about the volume of work. We also cover several exciting developments – in October we issued a revised draft guidance on communications by firms to health care providers of scientific information on unapproved use(s) of approved/cleared medical products, definitely a hot topic. In addition, our own Jason Cober moderated a DIA Roundtable Webinar on Responsive Search Ads – we've included a link to the recording and more information about the webinar in the What's New section below. To close out the month, OPDP issued two compliance actions and published a webpage to make it easier to find our Untitled Letters. In November, just before Thanksgiving, we finalized a rule about the presentation of the major statement in direct-to-consumer prescription drug ads in TV and radio format ("CCN"). In December, we updated our final guidance "Presenting Quantitative Efficacy and Risk Information in

Direct-to-Consumer (DTC) Promotional Labeling and Advertisements" to better reflect animal drug terminology and issued a Small Entity Compliance Guide to accompany the CCN final rule. You can find more details on each of these accomplishments below.

I'm pleased to share these updates with you, and I'm incredibly proud of the team. Rest assured OPDP isn't going to rest on our laurels – we have plenty more in the pipeline for you. Stay tuned for future updates!

Wishing you good health, happiness, and success in 2024!

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## Metrics Update

2023 Milestones

2023 marked another busy year for OPDP. Some notable trends and milestones include the following:

- Form FDA 2253 submissions increased by 3.8% over 2022 submissions. OPDP received over 67,000 Form FDA submissions in 2023.
- The number of individual promotional pieces submitted to OPDP held relatively steady, decreasing by 0.4%. OPDP received over 139,000 individual promotional pieces.
- OPDP issued 5 Compliance Letters in 2023. Four Compliance Letters were issued in 2022. Links to the Untitled Letters can be found here and Warning Letters can be found here.

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## Focus On Policy

### CCN Final Rule and Related Announcements:

On November 21, 2023, FDA issued a final rule to amend its prescription drug advertising regulations, entitled "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" (CCN Final Rule). The rulemaking implements a requirement of the Food, Drug, and Cosmetic Act (the FD&C Act), added by the Food and Drug Administration Amendments Act of 2007 (FDAAA, P.L. 110-85), that in human prescription drug ads presented directly to consumers in television

or radio format stating the name of the drug and its conditions of use, the statement relating to major side effects and contraindications ("major statement") must be presented in a clear, conspicuous, and neutral manner. As directed by FDAAA, FDA is establishing standards to help ensure that the major statement in these advertisements is presented in the manner required.

On December 26, 2023, FDA issued a final guidance entitled "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 Final Rule Questions and Answers". The final guidance was issued in accordance with the Small Business Regulatory Enforcement Fairness Act to help small businesses understand and comply with 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 Final Rule" (CCN Final Rule, issued November 21, 2023, 88 FR 80958).

This guidance is a Small Entity Compliance Guide (SECG) presented in a question-and-answer format that explains key provisions of the CCN Final Rule. The effective date of the final rule is May 20, 2024, and the compliance date is November 20, 2024.

Finally, the OPDP webpage has been updated to include new FAQs specific to the CCN Final Rule. You can find the new FAQs here: OPDP Frequently Asked Questions (FAQs).

## Guidance Announcements

On December 11, 2023, FDA published a revised final guidance for industry "Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer (DTC) Promotional Labeling and Advertisements." The guidance updates are minor and include the following revisions:

- In Section I, the term "over-the-counter animal drugs" has been replaced with the term "nonprescription animal drugs."
- Footnotes 3 and 5 have been revised to replace the term "over-the-counter animal drugs" with the term "nonprescription animal drugs"

On October 23, 2023, FDA issued a revised draft guidance entitled "Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products: Questions and Answers." This draft guidance supersedes the revised draft guidance issued in 2014 entitled "Distributing Scientific and Medical Publications on Unapproved New Uses – Recommended Practices."

This revised draft guidance, when finalized, will provide FDA's current thinking on common questions regarding certain communications by firms to health care providers (HCPs) of scientific information on unapproved use(s) (SIUU) of approved/cleared medical products. Specifically, this guidance relates to firms' sharing of the following types of communications with HCPs:

- Published scientific or medical journal articles (reprints)

- Published clinical reference resources, as follows:
    - Clinical practice guidelines (CPGs)
    - Scientific or medical reference texts (reference texts)
    - Materials from independent clinical practice resources

- Firm-generated presentations of scientific information from an accompanying published reprint

For the purposes of this guidance, these specific types of communications from firms to HCPs of scientific information on unapproved uses of certain approved/cleared medical products in combination with the disclosures recommended in this guidance are referred to as SIUU communications. Other communications by firms are not specifically addressed by this draft guidance, and the Agency does not intend to convey any views on such communications in issuing this draft guidance.

If a firm shares an SIUU communication with HCPs in a manner that is consistent with the recommendations in this guidance, FDA does not intend to use such communication standing alone as evidence of a new intended use.

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- On October 31, 2023, OPDP issued an Untitled Letter (UL) to Otsuka Pharmaceutical Development and Commercialization regarding the company's product Rexulti (brexpiprazole) tablets. The UL is posted on the OPDP Untitled Letters webpage. A copy of the UL can be downloaded at this link.
- On October 31, 2023, OPDP issued an Untitled Letter (UL) to Evofem Biosciences regarding the company's product Phexxi (lactic acid, citric acid, and potassium bitartrate) vaginal gel. The UL is posted on the OPDP Untitled Letters webpage. A copy of the UL can be downloaded at this link.

- On October 25, 2023, FDA published a new webpage displaying Untitled Letters issued by the Office of Prescription Drug Promotion (OPDP). The new webpage consolidates all OPDP Untitled Letters issued since 2017 onto a single webpage. Previously, OPDP Untitled Letters were displayed on separate webpages organized on the year the Untitled Letter was issued. OPDP Warning Letters will continue to be posted to the FDA Warning Letter webpage. OPDP Untitled Letters issued prior to 2017 will be available on the new Untitled Letter webpage through a link to the FDA Archive.

- On December 21, 2023, FDA announced a 60-day information collection titled "Examination of Implied Claims in Direct-to-Consumer Prescription Drug Promotion." Either electronic or written comments on the collection of information must be submitted by February 20, 2024**.** The Federal Register Notice can be downloaded here.

- On December 18, 2023, FDA announced a 30-day information collection titled "A Survey on Quantitative Claims in Direct-to-Consumer Prescription Drug Advertising." Either electronic or written comments on the collection of information must be submitted by January 17, 2024. The Federal Register Notice can be downloaded here.

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## In Case You Missed It

- On October 18, 2023, DIA hosted a roundtable webinar presenting best practices and recommendations when marketing prescription drug products through Responsive Search Ads (RSA). The roundtable panel included representatives from the regulatory affairs staff of two Firms and two speakers from a digital ad agency. The panel was moderated by Jason Cober, the OPDP Lead Project Manager. The panelists discussed the challenges presented by RSA and best practices for prescription drug marketers when creating marketing communications on paid search. DIA has posted a recording of the presentation at this link. The recording is free to access once you provide your contact information.

- On October 11, 2023, FDA announced a 60-day information collection titled "Adherence Potential and Patient Preference in Prescription Drug Promotion." The Federal Register Notice can be viewed here.

- The recording of the September 14th Duke-Margolis public meeting on the Future of Prescription Drug Promotion and Digital Marketing has been posted to the meeting webpage.

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## Where's OPDP?

- Keep an eye out for OPDP Office Director Catherine Gray, DPPRO Director Kathleen David and DPPRO Deputy Director Amy Muhlberg and their presentations at the upcoming DIA Advertising and Promotion Regulatory Affairs Conference on March 12-13, 2024.

- At the November 2-3, 2023 FDLI Advertising and Promotion for Medical Products Conference, OPDP Director Catherine Gray gave updates on regulatory advancements, and Amy Muhlberg and Helen Sullivan spoke on the

final guidance “Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer (DTC) Promotional Labeling and Advertisements.”

- OPDP Director Catherine Gray provided regulatory updates at the 24th Annual Pharmaceutical Compliance Forum (PCF) Pharmaceutical and Medical Device Ethics and Compliance Congress in October.

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

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OPDP Homepage

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



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