Gray Matters

Greetings! In conjunction with the New Year, I am excited to introduce OPDP's inaugural monthly newsletter, *The Brief Summary*. This OPDP communication will be a one stop hub for brief updates and newsy notes about OPDP staff and activities. As many of you already know, OPDP, one of two Offices in the Office of Medical Policy Super Office, is charged with protecting the public health by helping to ensure that prescription drug promotional communications are truthful, balanced and accurately communicated. *The Brief Summary* will serve as another tool to help realize this noble mission, enhancing communication with OPDP's stakeholders.

January traditionally brings the buzz of resolutions. Will you drink more water? Will you volunteer more in your community? Will you broaden your horizons with literature? Will you recommit to stronger compliance recommendations in your promotional reviews? OPDP, as individuals and a unified staff, commits to protecting the public health by embracing our core values of

mutual respect, diversity, high quality work, and a relentless pursuit of personal and professional growth. Our resolutions for 2022 lean heavily on these core values to promote enhanced stakeholder collaboration, meaningful communications, technology enhancements and world-class research.

We're looking forward to a new year of challenges and opportunities. As with any new year, we don't expect to have a shortage of either. We're excited to apply lessons learned from the pandemic and hoping to see that event in our rearview mirror as the year progresses.

Best wishes for health and happiness in this New Year. Good luck with your resolutions!

Cheers,

kbg

Get to know the Office of Prescription Drug Promotion

OPDP is led by Office Director Dr. Catherine (Katie) Gray who has served with the Office for 17 years. OPDP is separated into two Review Divisions (Divisions of Advertising and Promotion Review 1 and 2) which are comprised of nine teams of reviewers. These teams are responsible for the drafting of advisory letters, surveillance and compliance actions, and consultation services to the Office of New Drugs (OND). Each Review Team is aligned to an OND Review Division based on Drug Class. Additionally, the Office is supported by the Advertising and Promotion Policy Staff which is comprised of four discipline-specific teams: Policy, Project Management, Regulatory Counsel, and Social Science Research.

Engagement with OPDP can ensure better collaboration between Stakeholders and OPDP staff to facilitate timely responses from the Office. But how do stakeholders know who to contact when they need to engage with OPDP? If you know the OPDP Reviewer assigned to your prescription drug product, it's best to contact them directly for any review-related questions. If you don't know your assigned product reviewer or have general questions related to OPDP operations, please contact the

OPDP Regulatory Project Manager (RPM) mailbox at CDER-OPDP-RPM@fda.hhs.gov.

Core Launch Updates

In January 2021, OPDP updated the Core Launch Review Process to include a new 5-Business Day screening period. The new process allows reviewers to ensure submissions are complete and reviewable, and to assess if the materials qualify as "core" launch as defined in Section IV.C.1 of OPDP's guidance titled, "Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs." OPDP also posted a recorded webinar which provides additional details about the updated Core Launch review process.

As we begin the new year, OPDP is actively reviewing and analyzing the effectiveness of the new Core Launch Review Process and results from the first year have been outstanding. As the year progresses, we look forward to sharing more information about the Core Launch Review Process in this space. Stay tuned for exciting new updates!

OPDP Bad Ad Update

The OPDP Bad Ad Program kicked off 2021 with a renewed focus on healthcare provider (HCP) outreach and engagement. The prior year marked the Bad Ad Program's 10-year anniversary, and to date, the program has received over 2,100 reports of potentially false or misleading prescription drug promotion. In 2020, the Bad Ad Program updated its free online continuing education course and educational case studies to reflect changes to the prescription drug promotional landscape.

In 2021, the program published several new engagement pieces to help HCPs recognize and report potentially false or misleading prescription drug promotion:

- In March, OPDP Reviewer Ankur Kalola published an article in *Regulatory Focus* which discussed the regulatory landscape from the US Food and Drug Administration's (FDA) perspective as well as the Bad Ad Program's results and ongoing efforts to help promote the public health
- September marked the release of FDA's Bad Ad Social Media Quiz to test HCP knowledge of prescription drug promotion and OPDP's Bad Ad Program

- In September, Katie Gray and Ankur Kalola co-authored an article titled "FDA: Prescribers can help stop false or misleading prescription drug promotion" which published in *Healio*

HCPs can continue to report potentially false and misleading prescription drug promotion to OPDP by emailing BadAd@fda.gov, calling 855-RX-BADAD (855-792-2323), or write:

Bad Ad Program

FDA/CDER/OPDP

5901-B Ammendale Rd.

Beltsville, MD 20705-1266

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

OPDP Homepage