Gray Matters

Happy Winter! I hope you are all doing well as we get into the flow of the new year. Last month's edition of Gray Matters touched on New Year's resolutions, with a look forward to a new year of challenges and opportunities. Before we say our final adieu to 2021, I'd like to use this edition of Gray Matters to share with you some of OPDP's most notable accomplishments from this past year.

First, I'll touch on the pandemic and the resiliency of our staff. We said goodbye and good luck to some amazing colleagues in 2021, but we warmly welcomed new team members to our OPDP family as the year progressed. Staff eagerly took to mentoring and training our new colleagues. Amid the flux in personnel, our cadre of fantastic U.S. Public Health Service Commissioned Corps Officers answered the call to deploy many times in response to public health emergencies throughout the year. OPDP responded with an all-in approach: reviewers covered dockets and launches for deployed teammates; team leaders supported additional reviewers and took on

mentoring responsibilities; cross collaboration exploded and the laser focus on COVID response reverberated throughout the office.

Notwithstanding these challenges, OPDP delivered some outstanding accomplishments for the year. While future editions of *The Brief Summary* (*TBS)* will expand on these topics, I'll list a few headliners here:

- We instituted a new core launch review program, resulting in a significant decrease in the average time to issue a core launch advisory letter in 2021 compared to previous years.
- We hosted our first collaborative meeting with Duke Margolis. The meeting explored potential implications for prescription drug promotion as patients and healthcare providers increasingly use digital tools to inform and manage aspects of care, and drug manufacturers look to these tools to reach target audiences. Much of the discussion focused on identifying touchpoints where researchers both within and outside FDA can focus their attention in order to improve and safeguard the information that makes its way to patients and healthcare providers.
- We supported our Office of New Drugs (OND) colleagues in bringing critical new therapies into the fight against COVID-19.

These are but a few examples of the great work accomplished by our exceptional team in OPDP. Read on in *TBS* for a list of other notable deliverables. I am humbled and thankful for the opportunity to lead such a wonderful group of talented and dedicated professionals who support each other in the many ways we strive to protect the public health. Great things are in store as we settle into the new year. I hope you see the same on your horizon.

Best,

kbg

Staff Spotlight

Mark Askine - OPDP Deputy Director

I joined DDMAC (now OPDP) in 1996. I started as a regulatory review officer responsible for the diabetes, urology, anesthesia, and dermatology dockets. I assumed roles of increasing responsibility and scope, and I currently serve as OPDP's Deputy Director. The thing that I most enjoy about OPDP is having the honor to work with such an outstanding team. OPDP's work is always challenging and interesting to say the least, but the best part of the job always comes back to the blessing of working with such a talented, motivated, and deeply committed team of professionals.

I find OPDP's biggest impact is its ability to promote and protect public health by fostering better communication of labeling and promotional information to healthcare providers and consumers.

I pursued a career at FDA because it appealed to my skills and interests that weren't utilized to a great extent with traditional pharmacy practice. I began my FDA career in CDER's Division of Drug Information Resources, working on the Inactive Ingredient Guide, Drug Product Reference Guide, and the AIDS Clinical Trial Information Service. I also worked on the compounded drugs team and the unapproved new drugs team in CDER's Office of Compliance. I chose OPDP because its mission and culture align very closely with my core values.

I am a huge fan of the current Champions of Europe, Chelsea Football Club, and I enjoy golfing and traveling with my family.

Process Updates

OPDP constantly looks for ways to provide value and improve communication with our stakeholders. As part of our commitment to these goals, we recently updated our processes to apply a consistent approach to posting close-out letters for compliance actions, including untitled letters. Close-out letters for OPDP warning letters issued after January 1, 2017 are available on FDA's Warning Letters webpage. Users can find OPDP warning letters by using the webpage's filter function and entering "Office of Prescription Drug Promotion" in the Issuing Office field. OPDP's Untitled Letters 2021 webpage has been updated to include the close-out letters for untitled letters issued in 2021. OPDP intends to continue posting close-out letters, once issued, for warning and untitled letters.

2021 Milestones

2021 marked another busy year for OPDP. Some notable trends and milestones include the following:

- June 24, 2021 marked the end of the 24-month transition period for submitters to convert promotional submissions to eCTD format. Since July 2021, 99.6% of all submissions to OPDP have been in eCTD format.
- Form FDA 2253 submissions increased by 5% over 2020 submissions. OPDP received over 59,000 Form FDA 2253 submissions in 2021.
- The number of individual promotional communications submitted to OPDP increased by 7.5%. OPDP received over 145,000 individual promotional communications in 2021.
- OPDP issued 6 compliance letters in 2021, matching the number of compliance letters issued in 2020. Links to the 2021 compliance letters can be found on OPDP's website.
- OPDP staff who also serve in the United States Public Health Service Commissioned Corps deployed numerous times in support of critical public health missions.

- OPDP continued its outreach efforts by providing over 30 presentations at 15 virtual conferences in 2021.

Best Practices for Your OPDP Interactions

OPDP staff respond to thousands of inquiries each year, and some of the most common questions focus on the Accelerated Approval pathway. Applicants whose drug and biological products are being considered for approval or are approved under the Accelerated Approval pathway must pre-submit related draft promotional communications to OPDP prior to dissemination. The pre-submission requirement is defined in two regulations: 21 CFR 314.550 (Subpart H) and 21 CFR 601.45 (Subpart E). The regulations and submission requirements for promotional communications are discussed in greater detail in Section IV.B. of OPDP's guidance titled, "Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs" (Electronic Submissions Guidance).

What are some best practices when an Applicant's product receives Accelerated Approval designation?

- Early and frequent communication with your reviewer can help facilitate a smooth pre-submission process. Once an Applicant has been notified that its product will receive Accelerated Approval, a call to the assigned OPDP Reviewer can help answer any questions about the pre-submission process. If you don't know the OPDP Reviewer assigned to your product, you can email the OPDP RPM mailbox at CDER-OPDP-RPM@fda.hhs.gov.

- Applicants may voluntarily request comments on draft promotional communications related to a product's use as approved under the Accelerated Approval pathway. The draft promotional communication should be submitted separately from other draft promotional communications being pre-submitted for compliance with the Accelerated Approval regulations. The cover letter should clearly indicate that the Applicant is voluntarily seeking comments for an Accelerated Approval product.

- Note that Applicants must also submit to OPDP all final promotional communications related to a product's use as approved under the Accelerated Approval pathway to meet the post-marketing submission

requirement defined in 21 CFR 314.81(b)(3)(i). Final promotional communications must be submitted at the time of initial dissemination or publication using Form FDA 2253.

- Accelerated Approval pre-submissions are required in eCTD format. If an Applicant's eCTD publishing team has any questions about the structure or required file content for an Accelerated Approval pre-submission, they can contact OPDP's eCTD Team at OPDPeCTD@fda.hhs.gov. The OPDP eCTD Team can provide technical support for the eCTD submission process and review any test submissions the Applicant may choose to submit.
- The OPDP eCTD team has also prepared a How-To Video for eCTD Publishers. It provides an overview of the eCTD requirements for the pre-submission of draft promotional communications related to a product's use as approved under the Accelerated Approval pathway.

OPDP Electronic Submissions Update

The Electronic Submissions Guidance contains many recommendations for submitters. *The Brief Summary* will periodically feature the *OPDP Electronic Submissions Update* to provide responses to common questions received through the OPDP eCTD mailbox.

Q: Should firms address correspondence cover letters to a specific person when submitting promotional materials?

A: Section III of the Electronic Submissions Guidance states, "For OPDP, address submissions that require correspondences to the attention of the OPDP Project Manager."

Q: Should Form FDA 2253 submissions to OPDP include a cover letter?

A: Section IV.A of the Electronic Submissions Guidance states that Form FDA 2253 submissions should not include a cover letter or correspondence. Please do not include a cover letter with any Form FDA 2253 submissions in eCTD format. Submitters may use the Comments section of the Form FDA 2253 to communicate additional information to OPDP.

Read the full Electronic Submissions Guidance for additional recommendations related to promotional submissions to OPDP.

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