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OPDP Fun Facts: In 2021, OPDP received over 5,500 annotated promotional materials.

Gray Matters

June, and with it summer, arrives at my home along with a deep sigh and a lot of Dad jokes (that we good naturedly tolerate in honor of Father's Day). We've survived "Mayaos" (May + chaos) – the intense run around the bases – and slid hard across home plate. Now we're enjoying the leisurely stroll to the dug out. While this sentiment may be shared by some, others in the oncology sphere, for example, may instead see June as a full body collision at home plate between the base runner (the regulatory affairs professional) and the catcher (ASCO). Whether the dust settles at the end of May or the end of June, summer's generally more leisurely schedule may offer a chance to recover, recharge and reorganize.

As you consider a punch list for your summer dog days, I hope this month's *TBS* helps you organize your work and streamline processes. This issue highlights a few CFL considerations and tips for annotating submissions. You'll also meet another OPDP veteran who prefers winter sports to summer games.

Although I joke that summer is more relaxed, OPDP is always in the batter's box, ready for the next pitch. Or to use a Mark Askine-approved analogy, ready to receive an incredible cross at Stamford Bridge. While we're looking forward to days of more sunshine, and perhaps a game or two, we're always ready to engage with our stakeholders (and our fans!) in order to best serve the public health.

Wishing all the dads and the father figures in the stands a very Happy Father's Day! (And just to help you build your own immunity to dad jokes, I'll leave you with this… what do a mosquito and the Eiffel Tower have in common? They are both Paris sites!)

Best,

kbg

Roszet Untitled Letter

On June 2, 2022, OPDP issued an Untitled Letter (UL) to Althera Pharmaceuticals regarding the company's product Roszet. The UL is posted on the OPDP Untitled Letters 2022 webpage. A copy of the UL can be downloaded at this link.

Staff Spotlight

Ankur Kalola - Regulatory Reviewer

I earned my Pharm.D. from The Ernest Mario School of Pharmacy at Rutgers, The State University of New Jersey, and then completed a two-year postdoctoral pharmaceutical fellowship, focusing on regulatory advertising and promotion with Purdue University, Johnson & Johnson, and the FDA.

I joined the Office of Prescription Drug Promotion (OPDP) in 2013 after completing my post-doctoral fellowship. I am currently a regulatory review officer for metabolic and endocrine products and serve as the subject matter expert for OPDP's Bad Ad Program. I have found much fulfillment in working at the FDA because it has allowed me to contribute to the Agency's mission of protecting the public health at a broad level. Working on the Bad Ad Program has also provided me with the additional opportunity to help educate healthcare providers on prescription drug promotion. It is truly a pleasure working with similar scientific minded folks that are dedicated to the same mission. In my free time I love snowboarding, backpacking, and playing tennis.

Focus on Policy

In the dark about CFL? It's not just a type of lightbulb - read more to shed some light on what CFL means in the world of prescription drug promotion!

FDA-required medical product labeling does not include everything that is known about a product for its approved or cleared uses. So how can a firm share, including in their promotional communications, data and information about their product that is not contained in their product's FDA-required labeling but is consistent with the FDA-required labeling?

Start by checking out the recommendations in the “Medical Product Communications That are Consistent With the FDA-Required Labeling – Questions and Answers” Guidance for Industry, that’s how!

This Q&A format guidance describes how FDA determines whether a product communication is consistent with the FDA-Required Labeling (CFL) using a three-factor analysis.

But wait, there’s more! CFL is not the whole story – communications must still be truthful and not misleading. The guidance also provides general recommendations to aid firms in complying with the requirements in the FD&C Act and FDA’s implementing regulations for conveying information that is CFL in a truthful and non-misleading way, as well as examples to illustrate these concepts. In addition, the guidance clarifies for firms that FDA does not intend to rely on CFL product communications to establish a new intended use, different from the use(s) for which the product is legally marketed.

Read the full “Medical Product Communications That are Consistent With the FDA-Required Labeling – Questions and Answers” Guidance for Industry to learn more! We hope this information has been … illuminating. Check out future editions of *The Brief Summary* for more enlightening information!

OPDP Electronic Submissions Update

Annotations

Multiple sections of the “Providing Regulatory Submissions in Electronic and Non-Electronic Format — Promotional Labeling and Advertising Materials for Human Prescription Drugs” Guidance for Industry (Electronic Submissions Guidance) describe the content of specific submission types and contain directions to include annotated promotional materials. But how should Submitters structure and format annotations when submitting annotated promotional materials?

The Electronic Submissions Guidance includes instructions that describe what to include in a submission and in certain sections, submitters are directed to include the following items:

- An annotated copy of the proposed promotional material(s) that clearly identifies the source of support for each claim (e.g., specific page and lines of the PI or specific page and column/paragraph from other references)

- The most current FDA-approved PI and, if applicable, the FDA-approved patient labeling or Medication Guide with annotations cross-referenced to the proposed promotional material

- If applicable, annotated references to support product claims not contained in the PI, cross-referenced to the promotional material

Section VI provides additional details regarding annotated product labeling. Specifically, Section VI.G states the following:

> For draft promotional materials submitted (1) voluntarily for advisory comment, or (2) under 21 CFR 314.550 or 601.45, include the annotated product labeling in section 1.15.2.1.3. Firms should highlight and annotate, with a cross-reference to the promotional materials, the sections of the product labeling that are referred to in the promotional materials. When product labeling is used to support a claim or presentation in proposed promotional materials, hypertext links should be provided to the specific page that contains the supporting information.

For promotional materials submitted in fulfillment of the postmarketing reporting requirements, firms may choose to provide the annotated product labeling with hypertext links.

Section VI.H provides details on annotated copies of reference documents:

> If references are provided, submit each reference as an individual PDF file and place it in section 1.15.2.1.4. Firms should highlight and annotate, with a cross-reference to the promotional materials, the sections of the full reference that are referred to in the promotional materials. When a reference is used to support a claim or presentation in proposed promotional materials, firms should provide, in the annotated promotional material, hypertext links to the specific page of the reference that contains the supporting information.

For promotional materials submitted in fulfillment of the postmarketing reporting requirements, firms may choose to provide references with hypertext links. References improve the efficiency of review.

To help illustrate the recommended structure and format of the annotations described in the guidance, OPDP has posted a mock advertisement submission. The mock advertisement submission includes a clean copy of a fictitious promotional material, an annotated copy of the promotional material, and an annotated copy of the PPI. The annotated PPI demonstrates the requested cross-reference annotations described in the guidance. Different examples of methods for annotating have been included in the mock ad to show various ways a submission could be annotated. However, we recommend using a consistent method throughout your submission for all references included in the submission. It's important to note that while hypertext links are

requested in the guidance, they are not required. Nonetheless, including hypertext links in the annotations is encouraged and improves the efficiency of the review.

Additionally, the mock advertisement includes an example of a CFL three-factor analysis (see earlier/later piece on the CFL guidance). The CFL-analyses included in the mock annotated ad are examples of how optional CFL-analyses could be included to help facilitate OPDP's review of information not contained in the FDA-required labeling for the product but that may be consistent with the FDA-required labeling for the product.

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

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