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OPDP Director Outlines FDA's Social Media Plans, Promises Next Guidance on the Topic Coming 'Soon'

The FDA's chief architect of promotional policy promised at a recent conference that the agency would be issuing new guidance on social media promotion "soon."

During a Feb. 27 enforcement panel at the Drug Information Association's annual Marketing Pharmaceuticals conference in Washington, D.C., the head of the Center for Drug Evaluation and Research's Office of Prescription Drug Promotion (OPDP) detailed agency plans to issue new social media guidance this year. OPDP Director Tom Abrams told the roughly 250 conference attendees that the next two guidances being prepped by the agency would address promotion in formats with limited characters — such as Twitter and Facebook — and how companies can correct misinformation spread online by outside parties.

While Abrams declined to say exactly when his office will issue the guidances — which along with two other documents will form the crux of the agency's social media expectations (*see 1 below*) — he said he was "absolutely" confident they would be issued before the end of the year. This jibes with a guidance schedule issued in January that called for the agency to issue three social media guidances by the end of 2014 (*see 2 below*). The document listed the two planned guidances along with a third covering the proper usage of links.

"These are high, high priorities," Abrams told the crowd. "They're being worked on extensively, being well vetted, and when we do issue them — which we believe will be in the near future — they will be high quality products due to the reviews and vetting that goes into each one."

While Abrams didn't go into any details on the planned space limitation guidance, he provided an important tidbit on the misinformation guidance: it will be "completely voluntary," putting to rest a long-standing industry fear that companies could be held accountable for misinformation about their products coming from outside parties. According to Abrams, the guidance will outline best practices for companies that choose to correct information they encounter online being disseminated by third parties.

Much of Abrams' 25-minute presentation focused on OPDP's efforts to compel self-policing in industry. He noted that the office "puts more [resources] into voluntary compliance than enforcement" efforts, and while this has lead to an "overall improvement" in compliant industry promotions, OPDP still sees the need "to increase our efforts."

"We still see certain proposals and suggestions about promotion … that make us take a step back and think: 'Why is a company even thinking about going down that road?' Abrams said. "We want voluntary compliance to work. We don't want to issue a Warning Letter. But when we see a violative promotion … we will address it."

Speaking of which, Abrams devoted part of his presentation to examples of OPDP's enforcement efforts, covering two older Untitled Letters: an October letter to Sunivion Pharmaceuticals for a patient brochure (*see 3 below*) and a November letter issued to Daiichi Sankyo for a direct mailer (*see 4 below*). He did not reference the 10 other enforcement letters the office has issued since, including a contentious Warning Letter sent to Aegerion Pharmaceuticals over remarks made by its CEO on a cable investment show last year.

'Requests for Clarity'

Abrams also explained the rationale behind the office's unusual decision in November to amend and downgrade a 2012 final guidance on naming conventions to draft status (*see 5 below*), explaining that this was "to provide clarification" in response to multiple

See *Conference*, p. 2

Conference (continued from p. 1)

questions from industry on how to apply it in various scenarios.

"We got a lot of questions and a lot of requests for clarity," Abrams said of the guidance, which covers the appearance, size and prominence of product names in promotions. "So we took a step back and we issued a draft guidance to respond to those questions."

As an example, he noted that many in industry were baffled by the guidance's recommendations on how often to incorporate a product's established name (typically the generic or chemical name) in a piece, with some inferring that it should appear once per column, while others read the requirements as once for every two pages. To simplify things, the draft guidance tweaked the earlier recommendations by stating that one appearance of the established name per page or two-page spread was sufficient, provided it appeared alongside the most prominent example of the proprietary name.

The session ended with a question-and-answer session that focused mainly on the first of the social media guidances: a January draft guidance covering submission standards for online promotions of drugs, biologics and veterinary products (*see 6 below*). Abrams and fellow panelist Barbara Chong, who works in the director's office in OPDP, fielded half a dozen questions on the guidance, most concerning the draft guidance's recommendation that companies take responsibility for any promotions or claims that they can exert control or influence over.

Questioners posed multiple hypothetical scenarios where a company's influence on a promotion or claim is murky, such as advance knowledge but no involvement in the placement of a promotion on a third-party site, or promotional claims by a key opinion leader whose contract with the company has expired.

Abrams and Chong skirted these questions, saying that each case would "depend on the circumstances" and that there is "not a one-size-fits-all" answer.

Regarding the draft's recommendation that companies submit monthly updates to OPDP of all interactive content from publicly accessible websites, Chong noted that the draft performs a "balancing act" between providing OPDP with the information it needs and not overburdening industry with submission requirements.

Fellow panelist Lisa Stockbridge, who heads the Center for Biologics Evaluation and Research's Advertising and Promotional Labeling Branch (APLB), said that the draft would likely "reduce redundancy" in submissions to her department, since APLB routinely receives submissions for website promotions "four times a month."

"I think this will streamline things and make it a lot more efficient," she explained.

For More Information

1. See "DDMAC Delays First of the Social Media Guidances, Topic Expected To Cover One of Six Online Issues," February 2011, p. 3.
2. See "CDER's 2014 Agenda Includes Three Social Media Guidances, Revisions to Print and TV DTC Documents," March 2014, p. 5.
3. See "OPDP Untitled Letter Tackles COPD Drug Brochures," December 2013, p. 4.
4. See "OPDP Fires Off Warning Letter Over TV Interview; Untitled Letter Over Claims in Direct Mailing," January 2014, p. 3.
5. See "FDA Updates Guidance on Naming Conventions, Eases Expectations for Use of Established Name," January 2014, p. 2.
6. See "Draft Outlines Submission Standards for Interactive Promos, Including Real-Time Content," March 2014, p. 2. ❖