FDA Regulatory and Compliance Monthly Recap

JANUARY 2015

KEY FINDINGS

FDA's CDER, CDRH and CBER publish 2015 guidance agendas

The FDA's Center for Drug Evaluation and Research (CDER), Center for Devices and Radiological Health (CDRH), and Center for Biologics Evaluation and Research (CBER) have published their 2015 guidance agendas, identifying key topics for which Industry can expect direction this year.

The CDER's agenda includes 91 new or revised guidances in 14 categories ranging from Clinical/Statistical to Electronic Submissions. In the Advertising category, subjects include the recently released "Revised Draft Guidance on Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Human Prescription Drugs," as well as forthcoming guidances on pre-dissemination review for DTC TV ads, the use of healthcare economic information and providing submissions in electronic format. The agenda also includes a highly anticipated social media guidance on use of links that was laid over from 2014. The 2015 agenda provides a clearer picture of what manufacturers can expect from the guidance by extending its title to specify that it will deal with "Use of Links to Third-Party Sites." This social media guidance, along with one titled "Manufacturer Communications Regarding Unapproved Uses of Approved Medical Products," will likely confront some of the challenges Industry must manage when attempting to exercise the right to distribute truthful information about products while complying with strict regulations on manufacturers' speech.

At CDRH, the published agenda includes not only forthcoming new drafts but also plans to release final guidances. The agenda is prioritized according to an A-List of primary focus; a B-List that will be published as resources permit; and a list of guidances

from 10, 20 and 30 years ago that are subject to retrospective review. Among the draft guidance topics on the A- and B-Lists are several that deal with the regulation of digital health technologies. As a draft on general wellness products has already been released, it seems clear that the FDA intends to leave regulation of low-risk technologies that do not make health claims to FTC. Scheduled drafts also include "Benefit-Risk Factors to Consider when Reviewing IDE Submissions," "Informed Consent: Policy for Observational Data Used to Fulfill Device Requirements" and "Adaptive Design for Medical Device Clinical Studies," all of which have the potential to affect the path toward marketing clearance or approval.

CBER's agenda includes 11 draft and final guidances in three categories. The Blood and Blood Components section deals with such headline-hot issues as blood donor eligibility and the Ebola virus, while the Cellular, Tissue, and Gene Therapy category contains guidances on gene therapy and HCT/Ps. A single guidance occupies the third category. About electronic submissions, it is one of many that the FDA has released in recent years to bring its procedures into the Digital Age.

FDA to study limiting major statement in direct-to-consumer (DTC) TV ads amid concern that consumers are not comprehending risks

The FDA has been authorized to conduct a study attempting to assess concerns that, on the one hand, the current length of the major statement is too long for patients to absorb and that, on the other hand, current advertisements exclude risks that are important to patient decision-making.

As described in the Federal Register, there are currently "conflicting viewpoints" regarding the effectiveness of the required disclosure of risk information in direct-to-consumer broadcast drug advertisements. Accordingly, the FDA will examine the hypothesis that, "relative to inclusion of the full major statement, providing limited risk information along with the disclosure about additional risks will promote improved consumer perception and understanding of serious and actionable drug risks."

The study design, which will modify existing drug ads to be shown to study participants, was met with mixed reviews by Industry during the comment period. Although PhRMA raised concerns in its comment that this design could lead to confusion where participants have already viewed the unmodified ads outside of the study, the FDA has elected to "balance the integrity of the research with cost considerations" by including survey questions to control for ad familiarity. The FDA has added questions to the survey in response to AbbVie's comment, which suggested a question about how actionable the risk information is, and Pfizer's comment, which included a recommendation to assess clarity of the major statement and whether or not participants believe the right amount of risk information was presented.

Turning the conversation to an issue of regulatory authority, the Washington Legal Foundation questioned the FDA's standing to require a major statement at all. Its comment proposed that the study be expanded to yield data necessary to perform a First Amendment analysis of the condition that risk information be presented alongside benefit claims. The FDA declined to expand the scope of the study and added in a footnote, "We also note that we disagree with several aspects of the comment's assertions related to First Amendment law, but we do not believe it is necessary or appropriate to address those arguments here."

FDA opens Office of Pharmaceutical Quality (OPQ) to consolidate non-enforcement oversight of drug quality

The FDA reorganizes to "combine non-enforcement-related drug quality work into one super-office [OPQ], creating one quality voice and improving our oversight

of quality throughout the lifecycle of a drug product."

The FDA's new OPQ has opened, beginning its assumption of certain drug quality oversight functions from the Office of Pharmaceutical Science, Office of Compliance and Office of Translational Sciences in order to provide centralized quality supervision throughout the product life cycle. The FDA has clarified that the decision to reorganize was not motivated by an increase in quality issues but rather by the goal to prevent or mitigate quality issues so they do not lead to drug shortages that affect patients. Its vision is that the OPQ "will be a global benchmark for regulation of pharmaceutical quality" and establish standards for Industry, including clinical quality attributes and clinically relevant specifications that facilitate patient access to quality medications.

It is anticipated that the OPQ will maintain master data repositories and provide information from its surveillance to assist the Office of Regulatory Affairs in prioritizing and streamlining inspections. As acting director of the OPQ Lawrence Yu noted, "OPQ will work to balance regulatory resources between pre-marketing evaluation and post-marketing surveillance, and transform product quality oversight from a qualitative to a quantitative and expertise-based process."

FDA's CDRH issues draft guidance proposing not to regulate wellness products; defines when they become medical devices

CDRH releases draft guidance clarifying its intention not to evaluate "low risk products that promote a healthy lifestyle (general wellness products)" as medical devices.

CDRH does not intend to examine general wellness products like fitness trackers to see if they qualify as medical devices under the Food, Drug, and Cosmetic Act unless they make reference to diseases or conditions. This policy does not extend to devices that present inherent risk, including devices that raise novel questions of usability or biocompatibility. In order to help manufacturers determine whether their device qualifies as a general wellness product, the guidance includes a decision algorithm that asks yes-or-no questions to evaluate the device's health claims and level of risk.

With FTC's recent publication of its Staff Report on the Internet of Things and its enforcement action against a computer game manufacturer for making unsubstantiated (and potentially misbranding) health claims, it seems that the two regulators have started off 2015 with strong statements on who will regulate which aspects of the evolving digital health market.

FDA draft guidance provides framework for the classification and approval of medical device accessories

A new CDRH draft guidance helps disambiguate the regulation of device accessories by outlining intended application of classification policies and automatic Class III designation.

A device accessory may be classified by 1) inclusion in its parent device's classification order, 2) its own 510(k) premarket notification or PMA approval in the same class as its parent device, or 3) through a separate classification process seeking a class different from its parent device. With regard to these first two methods, the FDA states, "Classifying an accessory in the same class as its parent device is appropriate when the accessory, when used as intended, meets the criteria for placement in that class." For accessories that do not pose the same level of risk as their parents, however, the FDA encourages separate classification.

Accessories with substantially equivalent predicate devices can, of course, seek assignment to Class I or II independent of their parent device through the 510(k) pathway. New types of accessories seeking to be regulated as Class I or II, however, must utilize the *de novo* pathway to avoid automatic Class III

designation. The draft guidance describes the applicability of the *de novo* process to accessories and includes an appendix of information, such as proposed controls, that manufacturers should include in these *de novo* requests for accessory device classification.

For more information on any of these FDA regulatory and compliance updates, please contact Scott S. Liebman at sliebman@loeb.com.

Loeb & Loeb LLP's FDA Regulatory and Compliance Practice

Loeb & Loeb's FDA Regulatory and Compliance Practice comprises an interdisciplinary team of regulatory, corporate, patent and litigation attorneys who advise clients on the full spectrum of legal and business issues related to the distribution and commercialization, including marketing and promotion, of FDA-regulated products. Focusing on the health and life sciences industries, including pharmaceuticals, biologics, medical devices, wellness products, dietary supplements and organics, the practice counsels clients on regulatory issues, compliance-related matters and risk management strategies; advises on laws and regulations related to product advertising and labeling; counsels on FDA exclusivity policies and related Hatch-Waxman issues; and provides representation in licensing transactions and regulatory enforcement actions.