

E-ALERT | Food & Drug

April 28, 2010

SUMMARY OF FDA ADVERTISING AND PROMOTION ENFORCEMENT ACTIVITIES

MARCH 2010

This e-alert is part of a monthly series of e-alerts summarizing publicly-available FDA enforcement letters (i.e., warning letters and untitled letters) relating to the advertising and promotion of drugs, biologics, and medical devices. In March 2010, FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC) posted the following four enforcement letters (one untitled, three warning) on its website:¹

- Untitled Letter to Takeda Pharmaceuticals North America, Inc. re: Rozerem™ (ramelteon) Tablets (Jan. 28, 2010)²
- Warning Letter to Sirion Therapeutics, Inc. re: Durezol™ (difluprednate ophthalmic emulsion) 0.05% (Feb. 18, 2010)
- Warning Letter to Actavis US re: Kadian® (morphine extended-release) Capsules, CII (Feb. 18, 2010)
- Warning Letter to ISTA Pharmaceuticals re: XIBROM™ (bromfenac ophthalmic solution) 0.09% (Mar. 10, 2010)

The Advertising and Promotional Labeling Branch (APLB) in FDA's Center for Biologics Evaluation and Research posted the following two enforcement letters (both untitled) on its website:

- Untitled Letter to Talecris Biotherapeutics, Inc. re: Prolastin (Alpha1 Proteinase Inhibitor (Human)) (Mar. 5, 2010)
- Untitled Letter to CSL Behring LLC re: Zemaira (Alpha1 Proteinase Inhibitor (Human)) (Mar. 5, 2010)

The letters, taken together, make allegations under the following headings: Omission/Minimization of Risk Information; Misleading Claims; Unsubstantiated Claims; Broadening of Indication;

¹ Only enforcement letters posted to FDA's website in March 2010 are included herein. Letters issued in March but not posted to the website by March 31, 2010 will be summarized in our alerts for the months in which those letters are posted. As of the date of publication of this alert, the following additional letters, issued in March, have been posted on the DDMAC website: Warning Letter to Salix Pharmaceuticals, Inc. re: METOZOLV™ ODT (metoclopramide hydrochloride) orally disintegrating tablets (issued Mar. 19, 2010, posted Apr. 7, 2010); Warning Letter to Slate Pharmaceuticals, Inc. re: Testopel® Pellets (testosterone), CIII (issued Mar. 24, 2010, posted Apr. 16, 2010); Untitled Letter to Biogen Idec, Inc. re: TYSABRI® (natalizumab) injection for intravenous use (issued Mar. 25, 2010, posted Apr. 7, 2010); Untitled Letter to Gilead Sciences, Inc. re: Truvada® (emtricitabine and tenofovir disoproxil fumarate) Tablets (issued Mar. 26, 2010, posted Apr. 7, 2010); and Untitled Letter to Genentech, Inc. re: HERCEPTIN® (trastuzumab) Intravenous Infusion (issued Mar. 26, 2010, posted Apr. 23, 2010). The Center for Devices and Radiological Health (CDRH) did not post any applicable letters on its website in March.

² Dates referenced for the letters are issue dates.

Overstatement of Efficacy; Omission of Material Facts; and Misleading Patient Preference Claims. DDMAC's and APLB's letters conclude that the cited advertising/promotional issues render the subject products misbranded.

This alert merely summarizes the allegations contained in DDMAC's and APLB's letters. It does not contain any analysis, opinions, characterizations, or conclusions by or of Covington & Burling LLP. As a result, the information presented herein does not necessarily reflect the views of Covington & Burling LLP or any of its clients.

Omission/Minimization of Risk Information

FDA's letters contain several allegations under the "Omission/Minimization of Risk Information" heading. These include:

DDMAC untitled letter to Takeda Pharmaceuticals North America, Inc. (Jan. 28, 2010) ("Takeda Untitled Letter"): A substance abuse patient profile sell sheet for Rozerem™ (ramelteon) Tablets failed to present risk information with a prominence and readability reasonably comparable to the efficacy presentation. The first three pages of the four-page sell sheet contained numerous benefit claims, but the only specific risk disclosure was "relegated to the back cover." Additionally, the sell sheet failed to disclose "important risk information" associated with Rozerem, including WARNING information from the package insert (PI) about the risk of engaging in hazardous activities that require concentration (such as operating a motor vehicle or heavy machinery). The presentation also minimized risk by failing to present the risk of suicidality in conjunction with a statement on the administration of hypnotics to patients exhibiting signs and symptoms of depression. Finally, the sell sheet included a tagline that suggested the drug is safer than other sedatives/hypnotics merely because it is not scheduled by the U.S. Drug Enforcement Administration (DEA). Rozerem is associated with numerous risks, and its attribute as a nonscheduled drug does not alone confer "added safety."

DDMAC warning letter to Sirion Therapeutics, Inc. (Feb. 18, 2010) ("Sirion Warning Letter"): A professional sales aid for Durezol™ (difluprednate ophthalmic emulsion) 0.05% presented numerous efficacy claims on the front and back covers, and on pages 1-12 of the 16-page piece, but "fail[ed] to convey **any** risk information" specific to the drug on these pages. (emphasis added by DDMAC). The only specific risk disclosure was "relegated to the end of [the] sales aid on page 14." Furthermore, the risk presentation on page 14 omitted certain Contraindications and Warnings and Precautions from the package insert (PI). Page 13 of the sales aid contained a misleading safety presentation, which included claims and graphics that implied that an increase in intraocular pressure (IOP) is not a significant concern with Durezol treatment and served to minimize the serious risk of IOP increase reflected in Durezol's PI. The presentation was "particularly concerning because it suggest[ed] the use of Durezol for as long as 29 days" and the piece failed to reveal significant risks associated with such prolonged use of the drug.

Separately, a "z-card" for Durezol presented numerous efficacy claims, as well as "an assurance of safety – '**Demonstrated safety profile**' – but fail[ed] to include '**any** risk information.'" (emphasis added by DDMAC). The inclusion of the statement, "Please see full prescribing information for Important Safety Information," and the fact that the package insert (PI) for Durezol was printed on the back side of the unfolded z-card were not sufficient to provide appropriate qualification or pertinent information for the claims made in the promotional spread of the piece.

DDMAC warning letter to Actavis US (Feb. 18, 2010) ("Actavis Warning Letter"): A co-pay assistance program brochure and a comparison detailer for Kadian® (morphine extended-release) Capsules, CII presented several efficacy claims for the drug, but omitted its contraindications, as well as several

warnings, precautions, drug interactions, and adverse events. The comparison detailer also failed to present risk information with a prominence and readability reasonably comparable to the presentation of benefit information. The co-pay assistance program brochure minimized the risks associated with the use of Kadian by presenting “serious, potentially fatal risks” on the back cover in “highly complex, medically technical language that [was] not likely to be understood by consumers.” Inclusion of the statement, “**Please see accompanying complete Prescribing Information**” on various pages of the co-pay assistance program brochure and the comparison detailer did not mitigate the misleading omission and/or minimization of risk information in the pieces. (emphasis in original).

DDMAC warning letter to ISTA Pharmaceuticals, Inc. (Mar. 10, 2010) (“ISTA Warning Letter”): A professional sales aid for XIBROM™ (bromfenac ophthalmic solution) 0.09% omitted “serious and important warnings” regarding the potential for allergic reactions to sodium sulfite, including anaphylaxis and potentially life-threatening asthmatic episodes, cross-sensitivity reactions, and increased bleeding times. It also omitted “the most serious precautions” regarding slowed or delayed healing, increased risk for corneal adverse events in certain patient populations, and limitations on dosing. The sales aid “misleadingly minimize[d]” the risks associated with Xibrom by failing to present risk information with a prominence and readability reasonably comparable to the efficacy claims. Efficacy claims were presented using large font, bolded, colorful headers and colorful graphics, while the risk information, in contrast, was “relegated to the end of the aid” and presented in block paragraph format, without the use of headers or other signals to alert readers to its significance, and in a smaller font than the efficacy claims.

APLB untitled letter to Talecris Biotherapeutics, Inc. (Mar. 5, 2010) (“Talecris Untitled Letter”): A patient brochure for Prolastin (Alpha1 Proteinase Inhibitor (Human)) included multiple efficacy claims for the product, but failed to present the full contraindication for Prolastin. According to the Contraindications section of the package insert (PI), “[i]ndividuals with selective IgA deficiencies who have known antibody against IgA (anti-IgA antibody) should not receive Alpha1-Proteinase Inhibitor (Human), Prolastin, since these patients may experience severe reactions, including anaphylaxis, to IgA which may be present.” Although the brochure stated that individuals with selective IgA deficiencies should not receive Prolastin, it failed to include the “important information” that these patients may experience severe reactions, including anaphylaxis. Furthermore, the brochure had multiple pages of “easy to read benefit information” for Prolastin, but the “Important Safety Information,” was “difficult to read, presented in small font, with minimal white space, and presented in a blocked format on one-third of a page located on the second to last page of a 12-page brochure.”

Misleading Claims

FDA’s letters contain several allegations under the “Misleading Claims” heading. These include:

Takeda Untitled Letter: The sell sheet for Rozerem Tablets (discussed above) included the claim, “**One simple 8-mg dose.**” (emphasis in original; footnote omitted). This claim “misleadingly implicate[d]” that Rozerem’s dosing is “simple,” when this has not been proven with adequate evidence. As described in the DOSING AND ADMINISTRATION section of the package insert (PI), Rozerem dosing is associated with detailed instructions for use and multiple limitations and considerations, which do not support a “simple” dosing claim.

Talecris Untitled Letter: The patient brochure for Prolastin (discussed above) contained statements such as, “PROLASTIN is an augmentation therapy that helps **protect the lungs from damage**” and “**The Lung Preserver.**” (emphasis added by APLB). These claims were misleading because they implied a greater benefit for Prolastin-treated patients than is suggested by the package insert (PI) or by substantial evidence or substantial clinical experience. Furthermore, the Dosage and

Administration section of the PI specifically states that “the hypothesis that maintaining a serum level of antigenic alpha1-PI will restore protease-antiprotease balance and prevent further lung damage has never been tested in an adequately-powered clinical trial.”

APLB untitled letter to CSL Behring LLC (Mar. 5, 2010) (“CSL Behring Untitled Letter”): A sales aid for Zemaira (Alpha1 Proteinase Inhibitor (Human)) contained statements suggesting that the product would “slow decline of pulmonary function” or “reduce[] lung function decline.” Such claims were inconsistent with the package insert (PI) and misleadingly implied that Zemaira has demonstrated protective effects in the lungs or improved pulmonary function when this has not been demonstrated by substantial evidence or substantial clinical experience. According to the CLINICAL PHARMACOLOGY section of the PI, “the hypothesis that maintaining a serum level of antigenic A1-PI will restore protease-antiprotease balance and prevent further lung damage has never been tested in an adequately-powered controlled clinical trial.”

Separately, the sales aid for Zemaira presented the prominent, bolded headline, “**Unmatched purity. And peace of mind**” along with a comparative table of A1-PI protein (lot release and shelf-life specification) in Prolastin vs. Zemaira. The overall presentation misleadingly suggested that Zemaira is superior to or more effective than Prolastin based on a higher concentration of A1-PI protein when this has not been demonstrated by substantial evidence or substantial clinical experience. Additionally, the sales aid stated that “[i]n a retrospective analysis of the pivotal clinical trial data **Zemaira patients were 3 times less likely to experience COPD exacerbations** than Prolastin patients.” (emphasis added by APLB). These results were based on a retrospective analysis, and according to the Adverse Reactions section of the package insert (PI), “[n]o clinically significant differences were detected between the two treatment groups.” Likewise, the claim, “[d]uring clinical trials, **Zemaira patients reported 6 times fewer infusion-related events** than Prolastin patients” was misleading for the same reason. (emphasis added by APLB). The appearance of the disclaimer, “no clinically significant differences between the two treatment groups,” in a “very tiny footnote at the very bottom of the page” did not mitigate the overall misleading impression that the claims conveyed.

Unsubstantiated Claims

FDA’s letters contain several allegations under the “Unsubstantiated Claims” heading. These include:

Takeda Untitled Letter: The sell sheet for Rozerem Tablets (discussed above) contained the following claims, along with a graphic representation of the relative abuse liability of Rozerem and 18 other drugs: “**Rozerem is the only prescription insomnia medication with no evidence of abuse potential**” and “In a meta-analysis report evaluating abuse liability of 19 hypnotic compounds, only Rozerem demonstrated no likelihood of abuse and no detectable toxicity.” (emphasis in original). These claims and their accompanying presentation suggested that Rozerem has no likelihood of abuse and no toxicity, in contrast to the other 18 sedatives/hypnotics presented, and is therefore superior to the other drug products. FDA is not aware of substantial evidence or substantial clinical experience to support such claims. The inclusion of a footnote stating, “Results of a meta-analysis, not a head-to-head study...” was insufficient to mitigate the “misleading implication” created by the presentation. This presentation also minimized the risks associated with the use of Rozerem by implying that the drug has no toxicity associated with its use. This was “particularly concerning” because Rozerem is associated with numerous risks, including potential endocrine toxicity. Additionally, the presentation misleadingly suggested that Rozerem is a superior “prescription insomnia medication” as compared to the products listed, but the FDA-approved indications for the comparison products are different and the presentation failed to reveal these differences. The totality of the claims and presentations on the first page of the sell sheet also “misleadingly impl[ied]” that Rozerem is a superior insomnia treatment option for substance abuse patients

compared to the other sedative/hypnotic drugs based solely on the referenced drugs' attributes as benzodiazepine receptor agonists or Schedule IV controlled substances. FDA is not aware of substantial evidence or substantial clinical experience to support such a claim. In addition, this presentation omitted material information about other attributes of Rozerem therapy, including serious risks associated with its use.

Sirion Warning Letter: The professional sales aid for Durezol (discussed above) presented claims such as “Formulated for patient comfort,” “Emulsion formulation with no shaking required,” and “Durezol is a BAK-free product” under the heading, “**DESIGNED FOR PATIENTS.**” (emphasis in original). These claims implied that there are characteristics of Durezol that will have a positive impact on patient comfort with Durezol treatment. The claims also suggested that Durezol is superior to other ocular products that are not emulsion formulations or are not BAK-free. FDA is unaware of any substantial evidence or substantial clinical experience to support these implications. According to the package insert (PI), patients using Durezol experienced eye pain, photophobia, blepharitis, etc., as the most commonly reported adverse events, “any of which would undermine patient comfort.”

Actavis Warning Letter: The comparison detailer for Kadian Capsules (discussed above) misleadingly implied that Kadian has been shown to be superior to MS Contin® (morphine sulfate controlled-release) Tablets, CII and generic controlled-release morphine in that Kadian will provide less breakthrough pain, more consistent pain relief, and improved sleep scores. FDA is unaware of “any substantial evidence or substantial clinical experience that supports these claims or presentations.” (emphasis added by DDMAC). For example, DDMAC noted that the improved sleep score claims were “supported by a historically controlled study of inadequate design, completely lacking any concurrent control,” rendering the data “a completely meaningless comparison.” The comparison detailer also presented dosing claims that compared Kadian with both MS Contin and AVINZA® (morphine sulfate extended-release capsules), CII and implied that Kadian is superior to both drug products because Kadian’s dosage strength availability (i.e., eight dosage strengths) offers “fewer barriers to prescribing” and because Kadian has no immediate release component, no ceiling dose, and allows for 10 mg titration increments. FDA is unaware of any substantial clinical evidence or substantial clinical experience to support the claim that these characteristics “allow Kadian to have ‘fewer barriers to prescribing’ (the meaning of which is not clear) as compared to other extended-release morphine products.”

Separately, the co-pay assistance program brochure for Kadian Capsules included the claims: “Many Americans suffer from chronic or ongoing pain. It can cause you to miss work and can even keep you from enjoying life. If left untreated, pain can place stress on your body and your mental health...” and “Chronic pain . . . can be inconvenient and can keep you from your daily tasks.” Although Kadian may help treat patients’ moderate to severe pain, FDA is unaware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect the drug has in alleviating pain, taken together with any drug-related side effects patients may experience, results in an overall positive impact on a patient’s work, physical and mental functioning, daily activities, or enjoyment of life.

ISTA Warning Letter: The professional sales aid for Xibrom (discussed above) suggested that the drug is superior to other drugs in its class. This has not, however, been demonstrated by substantial evidence or substantial clinical experience. Page two of the sales aid presented claims and a chart comparing Xibrom’s potency against other ocular NSAIDs based on in vitro data. In vitro data, however, “are not a reliable predictor of the level of activity in the anterior chamber of the eye and no clinical significance of this data has been demonstrated.” The footnoted disclaimer, “*In vitro* study, the clinical significance is unknown” did not mitigate the “overwhelming misleading impression” created by the claims and the chart that Xibrom is superior to other drugs in its class.

Broadening of Indication

FDA's letters contain several allegations under the "Broadening of Indication" heading. These include:

Actavis Warning Letter: The co-pay assistance program brochure and the comparison detailer for Kadian Capsules (discussed above) failed to include the complete approved indication for the drug and presented broad claims about the drug's use in treating pain, therefore implying that Kadian is appropriate for use in a broader range of patients than it is approved to treat. Claims such as "**Improved pain control,**" and "**Less Pain. More Options,**" suggested that patients with broader types of pain than that for which the drug is indicated are appropriate candidates for Kadian therapy. (emphasis in original). These presentations (which appeared in both pieces) are "particularly concerning considering the serious and potentially fatal risks associated with the drug." Only a partial indication statement appeared on the brochure and on the comparison detailer, and both pieces omitted the important limitation indicating the "very limited patient population " for whom Kadian is appropriate. Inclusion of the statement, "**Please see accompanying complete Prescribing Information**" on various pages of the brochure and the comparison detailer did not mitigate the implication of the claims and presentations that "broadly promote[d] the use of this drug for any type of pain relief." (emphasis in original).

ISTA Warning Letter: The professional sales aid for Xibrom (discussed above) suggested that the drug is effective in a broader range of patients and conditions than has been demonstrated by substantial evidence or substantial clinical experience. The sales aid contained broad claims such as "XIBROM: Patients' Convenient Choice for Rapid Relief of Pain and Inflammation," which implied that the drug can be used for any ocular pain and inflammation. The drug is indicated only for the treatment of postoperative inflammation and reduction of ocular pain "**in patients who have undergone cataract extraction.**" (emphasis added by DDMAC). Furthermore, the claim "Bromfenac concentration available in **all ocular tissues,** with detectable levels through 24-hours," along with a graphic presentation, misleadingly suggested that Xibrom is effective for the treatment of pain and inflammation in all ocular tissues when this is not the case. (emphasis added by DDMAC). Xibrom has been demonstrated to be effective only in treating inflammation and associated pain following cataract surgery, which implicates the cornea and iris-ciliary body, but not other ocular tissues. Additionally, the sales aid claimed that Xibrom is "The Preferred Choice" and contained a graph of patient dosing preference comparing the twice daily dosing of Xibrom to the dosing of other ocular NSAIDs. The totality of these claims and presentations implied that Xibrom is a safe and effective alternative, and one that is preferred by patients for any of the uses of these other ocular NSAIDs when this is not the case. The comparison products had different indications. Although the approved indication for Xibrom was provided at the bottom of the first page of the sales aid, it was presented "without prominence in very small font compared to the large, bold, and colorful claims and graphs suggesting that Xibrom can be used for any ocular pain and inflammation."

Overstatement of Efficacy

FDA's letters contain several allegations under the "Overstatement of Efficacy" heading. These include:

Sirion Warning Letter: The professional sales aid and the z-card for Durezol (discussed above) included claims and presentations that misleadingly suggested that patients treated with Durezol will achieve complete resolution of inflammation and pain even though the Durezol package insert (PI) does not include evidence to support these claims. The sales aid also contained claims and presentations indicating the degree of ocular clearing experienced by patients receiving Durezol. The definition of "clearing" used in the sales aid, however, was inconsistent with the efficacy information

in the Durezol PI and misrepresented the FDA-defined criteria for clearing of inflammation. The overall presentation “significantly overstate[d] the demonstrated efficacy of Durezol.” The sales aid also presented efficacy claims that were derived from a clinical study using an unapproved dosing regimen for Durezol. The presentations in the sales aid came from a study of patients receiving Durezol QID one day prior to surgery; however, Durezol is approved only for use following surgery. These claims and presentations overstated product efficacy and also constituted the promotion of an unapproved dosing regimen for Durezol.

ISTA Warning Letter: The professional sales aid for Xibrom (discussed above) suggested that Xibrom is more effective than has been demonstrated by substantial evidence or substantial clinical experience. The claim, “XIBROM: Rapidly Relieves Pain and Inflammation with Just Two Days of Treatment” was misleading because it implied that patients receiving Xibrom experienced significant relief of inflammation after two days of treatment when this has not been demonstrated by substantial evidence or substantial clinical experience. According to the reference cited, only 8.4% of subjects receiving bromfenac had cleared or trace ocular inflammation three days after surgery. Additionally, according to the package insert (PI), only 62-64% of patients receiving Xibrom experienced reduction of ocular inflammation to trace inflammation or clearing by 14 days post-surgery. Therefore, few patients experienced relief of inflammation two days after treatment initiation and many patients did not experience clearing of inflammation after two weeks.

Omission of Material Facts

FDA’s letters contain several allegations under the “Omission of Material Facts” heading. These include:

Takeda Untitled Letter: The header on the back cover of the sell sheet for Rozerem Tablets (discussed above) included the claim, “**You can prescribe Rozerem for as long as you need to**” with a footnote stating, “Rozerem is indicated for the treatment of insomnia characterized by difficulty with sleep onset. Rozerem can be prescribed for long-term use.” (emphasis in original). This claim “misleadingly omit[ted] important contextual information regarding the long-term use of Rozerem.” The WARNINGS section of the package insert (PI) cautions that the failure of insomnia to remit after a reasonable period of treatment may indicate the presence of a primary psychiatric and/or medical illness that should be evaluated. Although the “Important safety information” section of the sell sheet contained a statement recommending that failure of insomnia to remit after a reasonable period of time should be medically evaluated, this sentence was “buried in the risk presentation on the back cover of the piece” and thus insufficient to provide context for the prominent long-term use claim.

ISTA Warning Letter: The professional sales aid for Xibrom (discussed above) failed to reveal important limitations to the dosing of the drug. Although it stated that Xibrom is administered twice daily, it failed to reveal that Xibrom should be applied beginning 24 hours after cataract surgery and only continued through the first two weeks of the postoperative period. This omission is “concerning” because, according to the Precautions section of the packager insert (PI), use of topical NSAIDs beyond 14 days postsurgery may increase patient risk for the occurrence and severity of corneal adverse events.

Misleading Patient Preference Claims

FDA’s letters contained the following allegations under the “Misleading Patient Preference Claims” heading:

ISTA Warning Letter: The professional sales aid for Xibrom (discussed above) implied that patients prefer Xibrom to other ophthalmic NSAIDs. However, DDMAC is not aware of substantial evidence or substantial clinical experience to support this claim. The sales aid included claims such as “The Preferred Choice” and “99% of patients (1,707 patients) preferred twice daily dosing over other dosing regimens.” The reference cited in support of these claims was a survey undertaken to evaluate physician and patient satisfaction with Xibrom and its comfort profile in normal clinical practice. The survey does not provide substantial evidence to support patient preference claims for several reasons. First, the survey included only subjects on Xibrom and therefore, no comparison products were implicated. Second, patient preference is a patient-reported outcome that implies a measurement of an aspect of a patient’s health status that comes directly from the patient. The responses to these survey questions, however, were based only on the physicians’ determination (not the patients’ determinations) for the categories surveyed. The responses may therefore have been unduly influenced by the assessments or judgments of the physicians. Third, the broad concept of overall patient preference is not adequately measured by just the six items on the survey because these items did not adequately address other important determinants of patient preference such as convenience, dosing, dosage form, efficacy, and adverse events. In addition to broad patient preference claims, the sales aid included “patient dosing preference” claims and presentations implying that patients prefer Xibrom to other ophthalmic NSAIDs that are dosed more frequently. The reference cited in support of these claims was a patient survey conducted via a coupon that asked, “If you could pick a prescription eye drop, which best fits your needs?” The results from this survey do not support claims that patients prefer Xibrom over more frequently dosed ophthalmic NSAIDs because responses to a general hypothetical question are insufficient to assess patient preference for one particular dosing regimen over another. Moreover patient preference is influenced by more than just the dosing regimen of a drug. Patient preference claims should be supported by well-designed and controlled head-to-head studies using well-developed instruments that can evaluate all determinants of patient preference. Furthermore, the claim, “XIBROM: Patients’ Convenient Choice for Rapid Relief of Pain and Inflammation,” which appears as a tagline near the end of the sale aid, was misleading because it broadly asserted that, overall, treatment with Xibrom will be “convenient” for patients. When considering all aspects of convenience, including the risks associated with the drug (some of which may be sight-threatening) and the method of administration of Xibrom, it is not self-evident that this broad claim of overall convenience is supported.

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If you have any questions concerning the material discussed in this client alert, please contact the following members of our food & drug practice group:

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