KING & SPALDING

Client Alert

FDA & Life Sciences Practice Group

March 22, 2011

2010 Year in Review: DDMAC and APLB Warning Letters and Untitled Letters

In 2010, the CDER Division of Drug Marketing, Advertising, and Communications (DDMAC) issued a total of 52 enforcement letters to pharmaceutical and biologics manufacturers, 14 more than in 2009. Of the 52 letters issued by DDMAC, 13 were Warning Letters and 39 were Untitled Letters. Eighteen of DDMAC's enforcement letters were issued regarding drugs with boxed warnings, including three Warning letters (23% of all warning letters) and 15 Untitled letters (38% of all untitled letters). The Advertising and Promotional Labeling Branch of CBER (APLB) issued only six enforcement letters in 2010, the same number as in the two previous years. Of the six letters issued by APLB, one was a Warning Letter and five were Untitled Letters.

Notable Trends in 2010:

A number of trends emerged in 2010:

- Internet-related promotional media continue to be a significant area of focus, with thirteen letters issued for claims made in emails, websites, website videos, social media, and/or webcasts.
- Videos, whether on websites or in other promotional contexts, were a focus of FDA enforcement efforts. Eight Warning Letters scrutinized the content and format of promotional videos.
- One (and only so far) Untitled Letter focused on shared media generated by a Facebook widget, signaling the start of enforcement efforts in the area of social media.

The most frequent allegations cited by DDMAC in 2010 were:

Allegation	2010	2009
Omission and Minimization of Risk Information	85%	86%
Broadening, Omission, or Misleading Indication	40%	56%
Overstatement of Efficacy	63%	37%
Unsubstantiated or Misleading Comparative or Superiority Claim	46%	23%

For more information, contact:

Nikki Reeves
+1 202 661 7850
nreeves@kslaw.com

Christina M. Markus
+1 202 626 2926
cmarkus@kslaw.com

Elaine Tseng
+1 415 318 1240
etseng@kslaw.com

Joanne H. Chan
+1 202 626 2914
jchan@kslaw.com

King & Spalding
Washington, D.C.
1700 Pennsylvania Avenue, NW
Washington, D.C. 20006-4707
Tel: +1 202 737 0500
Fax: +1 202 626 3737

www.kslaw.com

Observations and Lessons Learned from 2010 FDA DDMAC and APLB Letters:

- ***FDA continues to find links or references to full prescribing information to be inadequate communication of risk information.*** Consistent with the FDA's focus on the omission and minimization of risk information in promotional materials, FDA continues to find links to prescribing information to be inadequate communication of risk information. Most promotional materials that were the subject of enforcement letters contained disclaimers, caveats, references to full prescribing or risk information, or links to full prescribing and risk information, but FDA did not consider these strategies to effectively achieve fair balance in the representation of risk information.

- ***Nearly half the letters focus on drugs with boxed warnings or REMS.*** Of the 52 letters issued by DDMAC, almost half—21 letters—were issued in connection with drugs that either have a boxed warning or are subject to a REMS. The high percentage of letters underscores FDA's heightened scrutiny of promotional materials for drugs that, from FDA's perspective, have an increased safety risk.

- ***FDA is starting enforcement against promotion in social media.*** In 2010, FDA issued one Untitled Letter relating to shared content generated by a Facebook widget—suggesting FDA is beginning to examine social media promotion and set policy in the absence of guidance documents through enforcement action. So far, social media promotion appears to be held to the same requirements regarding presentation of risk and indication information as for other media.

- ***FDA continues to sporadically review oral statements made by sales representatives.*** FDA continues to review oral statements made by company representatives at conferences. Two enforcement letters issued in 2010 were to companies for oral statements made by their respective sales representatives at the 2009 American Society of Health-System Pharmacists Midyear Clinical Meeting and Exhibition in Las Vegas. This compares to one enforcement letter issued in 2009 to a company regarding oral statements by a sales representative at another conference.

- ***FDA is closely scrutinizing clinical studies cited in support of claims and statements.*** Numerous enforcement letters found promotional materials to be false or misleading based on the design of studies cited in support of claims or statements. In particular, FDA paid close attention to the type of study (*e.g.*, whether or not studies were randomized or head-to-head comparisons) and whether the specific endpoints examined in the studies adequately supported the promotional claims.

For your reference, we prepared a chart that provides: (1) a list of 2010 DDMAC and APLB letters, and (2) highlights of promotional violations alleged in each letter. The chart is available online in a searchable PDF document at: http://www.kslaw.com/library/publication/ca032211_chart.pdf.