

Regulatory Alert FDA's First Facebook Enforcement Action

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EXECUTIVE SUMMARY

FDA's citation of Novartis' use of the Facebook Share function on its Tasigna® website – while providing some welcome assurance that FDA does not intend to hold pharma marketers responsible for comments made in social media by others – does clarify that FDA continues to regard fair balance on-page (not one click away) as mandatory in all media, including space-limited social-media vehicles. Digitas Health advises pharma marketers wishing to incorporate this valuable functionality into their websites to ensure that shared content is constructed in either “help-seeking” form, referencing the indication, but not containing the product name, or in “reminder” form, containing the product name but making no representations about the product.

BACKGROUND

The Food and Drug Administration (FDA) has taken its first enforcement action against a pharmaceutical company for its use of Facebook. This regulatory action comes 10 months after the FDA held Part 15 hearings on the use of social media and before the guidance anticipated as a result of those hearings has been issued.¹

This single enforcement action does NOT answer all of the questions raised during the social media hearings or about the use of social media in general. It does, however, clarify some issues; and pharmaceutical companies would be well advised to assume that this enforcement action establishes precedent applying to future social media activities.

In addition, FDA explicitly mentions that other social media applications used for sharing “raise similar issues,” thereby expanding the applicability of this enforcement action beyond Facebook.² Finally, because the Facebook Share feature takes advantage of metadata established by the pharmaceutical company for search and other purposes, this enforcement action also expands responsibility for 2253 filing and compliance checking to the metadata on websites.³

RELEVANT FACTS

On August 3, 2010, FDA's Division of Drug Marketing Advertising and Communications (DDMAC) posted to the FDA website an untitled letter that had been sent to Novartis Pharmaceuticals on July 29, 2010, regarding its use of the Facebook Share tool on the US website for Tasigna (nilotinib) (www.us.tasigna.com).

At the time of the initially cited communications, Tasigna was “indicated for the treatment of chronic phase and accelerated phase Philadelphia chromosome positive [Ph+] chronic myelogenous leukemia (CML) in adult patients resistant or intolerant to prior therapy that included imatinib.”⁴

Subsequently, Tasigna received additional approval from the FDA under 21 CFR 314 Subpart H for the “treatment of newly diagnosed adult patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase.”⁵

Based on the promotional materials posted with the letter, the Tasigna website featured a button that enabled users to “share” on their personal Facebook page an image, a description of a web page, and a link to the webpage – all content created by Novartis. The FDA letter stipulates that the content could NOT “be

modified by Facebook users who use[d] this Facebook Share social media widget.”^{6,7} And importantly while FDA did note that it was possible for users to append their own comments to the Novartis content, none of the violations cited in this letter involved user-generated comments, nor was any statutory basis for holding such user comments as violative adduced.

The descriptive content displayed by Facebook on the user’s page via the Share feature pulled from the website metadata, which is invisible to most users but relied on by search engines, such as Google, Yahoo!®, and Bing™, to provide a description of the page’s content.⁸

VIOLATIONS CITED

FDA cited Novartis for four specific violations:

1. Omission of Risk

As it has repeatedly asserted in previous enforcement actions, DDMAC reminded Novartis that whenever a communication provides information about the benefit(s) of a product it must also provide risk information, and it must do so “in each part” of the communication where benefit information is provided.⁹

DDMAC reiterated its position – first enunciated in March, 2009, with respect to paid search listings – that it does NOT satisfy the company’s compliance requirement to include a hyperlink to a webpage where risk information is included.¹⁰

DDMAC did not specify what level of disclosure they regarded as mandatory – full PI, Brief Summary, or “major statement”: (aka Important Safety Information or ISI) – but the letter emphasized that the content provided by Novartis would in any event be violative because it “fail[ed] to communicate any risk information” (emphasis in the original).^{11,12}

Hints about FDA’s expected level of disclosure can be discerned in the letter’s statement that “materials are misleading if they fail to reveal facts that are **material** in light of the representations.” (emphasis added)¹³ This explicitly mirrors language used by the FDA in its draft *Guidance for Industry: Presenting Risk Information in Prescription Drug and Medical Device Promotion*, where FDA quotes from the Code of Federal Regulations to emphasize the need to “**reveal material facts** about ‘consequences that may result 797 from the use of the drug as recommended or suggested in the advertisement.’ 21 CFR 202.1(e)(5)” (emphasis added).¹⁴

Thus, while FDA has not stated definitively whether presentation of benefit information in social media requires complete risk information or something analogous to the ISI or the “major statement” in broadcast advertising,¹⁵ it appears to be leaning toward the latter.

2. Broadening of Indication

Tasigna’s indication, at the time of initial communication, was limited to patients with chronic-phase and accelerated-phase Philadelphia-chromosome-positive [Ph+] chronic myelogenous leukemia (CML) who were resistant or intolerant to prior therapy that included imatinib. DDMAC noted, however, that the Novartis content displayed on the user’s page when the Share function was invoked failed to include these important limitations to the indication and thus implied that Tasigna was appropriate for a broader population.

This broadening-of-indication citation re-iterates well-established FDA principles applying to all media. Its specific relevance to social media relate to the brevity of communication that is typically encouraged – and sometimes required by – social media.

Facebook’s Share function displays up to 100 characters of a page’s title and 121 characters of text from the page’s metadata description (or copy on the page if no metadata description is provided).¹⁶

These limitations notwithstanding, DDMAC’s enforcement action clearly indicates that even in these contexts, the FDA expects an accurate and complete description of the approved indication.

3. Unsubstantiated Superiority Claims/Overstatement of Efficacy

This violation, citing the use of the phrase “next-generation treatment” as implying a superiority claim for which there is not substantial evidence, has no specific relevance to social media, per se. The phrase would have been found equally violative in the context of a sales aid or patient brochure as in a Facebook post, so this particular violation does not appear to add anything specific to our understanding of how DDMAC will regulate social media, other than to emphasize that the same rules apply to social media as to other media.

4. Failure to Submit (under cover of Form 2253 or 30 days prior to use)

One of the more vexing concerns surrounding social media is how to deal with the real-time nature of social media conversations while complying with the FDA’s requirements to file materials at the time of initial dissemination.¹⁷ In taking this enforcement action, FDA has clarified its view about this requirement.

In the enforcement letter, FDA stated that Novartis failed to “submit specimens of any labeling or advertising ... of a drug product approved under Subpart H regulations at least 30 days prior to the intended time of initial dissemination ...[and for non-Subpart H products] at the time of initial dissemination....”¹⁸ This would appear to be a straightforward failure of compliance with mandatory submission requirements, again without specific relevance to social media.

It is worth noting, however, that FDA limited the scope of the failure-to-submit violation to “the **shared content**” (emphasis added).¹⁹ In other words, given the opportunity to extend the violation from a failure to submit the shared content generated by Novartis itself to requiring submission of all subsequent **repostings** by Facebook users, DDMAC declined to do so. Instead, it chose the reasonable path of holding the pharmaceutical company responsible solely for submitting the content it generated – a stance that many in the industry have long advocated²⁰ and consistent with statements made by FDA panel members at the November, 2009 Part 15 hearings.

KEY POINTS

1. FDA explicitly stated that many of the concerns raised in this enforcement action apply equally to other social media tools for sharing information. The lessons of this enforcement action apply to **all social media**, not just Facebook.
2. FDA explicitly stated that it was the **content generated by Novartis** that prompted this enforcement action, not any additional comments or messages by users. In doing so, FDA seems more explicitly to be endorsing the view that it will hold pharmaceutical companies accountable solely for the material they provide for use in social media venues, not for any comments made about that material. This position is entirely consistent with previous FDA statements, as well as the limits of their statutory authority, and it should help allay the fear among some in industry that they will be held accountable for the actions of others.
3. Phrases containing implied claims, such as “next generation,” without substantial evidence to support their use are inherently risky in all media, and social media is no exception.²¹
4. DDMAC applied the principle of holding pharmaceutical companies accountable for filing only those materials generated by the pharmaceutical company.
5. However, DDMAC expects companies to provide metadata as part of the 2253 filing requirements.

6. DDMAC is applying the principle of fair balance to metadata descriptions, and continues to make no exception for limited-space social media vehicles.

RECOMMENDATIONS

1. Because the brevity of the character-count limitations of the Facebook Share functionality will, in most cases, make a “full product communication,” containing (a) the brand and generic name of the drug; (b) the complete indication; and (c) the “material” risk information impracticable, Digitas Health recommends that Facebook Share content on brand websites be constructed in either –
 - a. **Reminder Format**, in which the product brand and generic names are mentioned, but no claims or representations are made about the product, or
 - b. **Help-Seeking Format**, in which the condition(s) treated by the product are mentioned, but no mention is made of the product name.
2. Where Facebook Share functionality will be included on a pharma website, planning for regulatory submission should include 2253 submission, not only of actual website content but of the shared content as it will appear on a Facebook user’s page. In the case of Subpart H products, this content will need to be submitted 30 days prior to dissemination.
3. Because website metadata is used both by search engines in generating organic search listings and by social media channels, such as the Facebook Share functionality, Digitas Health advocates that all site metadata should be included in internal medical/legal/regulatory review and as part of mandatory FDA submissions.

REFERENCES

The letter to Novartis was accessed on August 4, 2010 from

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm197224.htm>

1. The CDER Guidance Agenda posted on January 29, 2010, lists a guidance concerning “Promotion of Prescription Drug Products Using Social Media Tools” as scheduled for issuance during 2010. In several presentations this year, high-ranking officials at DDMAC, including Director Tom Abrams at the Drug Information Association’s annual meeting on June 15 (<http://pharmamktg.blogspot.com/2010/06/i-predicted-it-social-media-guidance.html>) and Jean Ah-Kang, Special Assistant to the Director, at the Social Media Tools conference on June 22, 2010, have affirmed DDMAC’s intention to release a guidance in 2010, though its scope is still to be determined.
2. See footnote 3, page 1 to letter sent July 29, 2010, to Novartis for Tassigna (nilotinib) MACMIS # 18870. Last accessed August 4, 2010, from <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm197224.htm>
3. Note that this is NOT the first time DDMAC has issued a letter related to metadata. Sanofi-aventis received a letter (MACMIS ID # 17325) on March 26, 2009, for marketing PLAVIX® (clopidogrel bisulfate) Tablets. The letter received little comment at the time because it was released on the same day as 13 other letters relating to paid search engine marketing. Few people noticed that the infraction cited by DDMAC related to **organic, non-paid** search engine results.
4. MACMIS #18870, page
5. MACMIS #18870 footnote 4, page 2.
6. MACMIS #18870 footnote 2, page 1.
7. For a description of how the Facebook Share feature functions, see http://wiki.developers.facebook.com/index.php/Connect/Using_Facebook_Share
8. For a detailed, technical discussion of how to improve what content is posted via the Facebook Share feature, see <http://www.whoisgregg.com/blog/2009/05/optimizing-for-facebook-share-preview.html> Accessed on August 5, 2010.
9. MACMIS #18870, page 3.
10. This stance by DDMAC has been consistently maintained in numerous enforcement actions going back at least to the letter sent to Novartis Pharmaceuticals for Internet banner ads promoting Diovan (valsartan) Tablets, dated August 28, 2008, MACMIS ID # 16734.

11. See Draft Guidance for Industry Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements for a complete discussion of the Brief Summary requirements. Last accessed August 4, 2010, from <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm064956.htm>
12. MACMIS #18870, page 3.
13. MACMIS #18870, page 2.
14. Page 23. Last accessed June 21, 2010, from <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm064956.htm>
15. For the major statement requirement, see 21 CFR 202.1.
16. Facebook's description of the Share feature was last accessed on August 5, 2010, from http://wiki.developers.facebook.com/index.php/Connect/Using_Facebook_Share. For the character limits used by Facebook's Share feature, see <http://www.whoisgregg.com/blog/2009/05/optimizing-for-facebook-share-preview.html>
Accessed August 5, 2010.
17. Note that DDMAC refers to the requirement to submit materials 30 days in advance of use in its letter to Novartis because Tasigna was initially approved under 21 CFR 314 Subpart H, and its approval for first-line use is also under Subpart H. That requirement does not apply to most pharmaceutical products, and the primary implications of the violation discussed in this section apply regardless of whether a product is approved under Subpart H.
18. MACMIS #18870, page 5.
19. MACMIS #18870, page 5.
20. Note that this appears to follow the recommendations provided by Publicis Groupe to the FDA regarding the 2253 filing requirements in response to the Part 15 Social Media hearings held on November, 12-13, 2010. See <http://www.regulations.gov/search/Regs/home.html#documentDetail?R=0900006480aaefec> for those comments. Last accessed, August 5, 2010.
21. MACMIS #18870, footnote 5, page 5.