



# Social Media Draft Guidance Webinar

July 10, 2014



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# Presenters

- **Thomas Abrams** – Introductory Remarks
- **Barbara Chong** – Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics (Draft Guidance)
- **Jean-Ah Kang** – Internet/Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices (Draft Guidance)
- **Julie Chronis** – Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices (Draft Guidance)



**Draft Guidance for Industry:**  
*Fulfilling Regulatory Requirements for  
Postmarketing Submissions of Interactive  
Promotional Media for Prescription  
Human and Animal Drugs and Biologics*

***Barbara Chong, Pharm.D.***

Office of Prescription Drug Promotion

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# Outline

- Describe FDA's current thinking about how firms can fulfill the regulatory requirements for postmarketing submissions of interactive promotional media for their FDA-approved drug products
- Discuss the factors taken into consideration to determine if product communications using interactive technologies are subject to FDA's postmarketing submission requirements
- Provide FDA's recommendations for submitting interactive promotional materials

# Definitions

- ***Interactive promotional media*** includes modern tools and technologies that often allow for real-time communications and interactions (e.g., blogs, microblogs, social networking sites, online communities, and live podcasts) that firms use to promote their drugs
- ***Drugs*** include prescription human and animal drug and biological products

## Factors in Determining Postmarketing Submission Requirements for Interactive Promotional Media

- Agency considers whether the firm, or anyone acting on its behalf, is influencing or controlling the promotional activity or communication
- A firm is responsible for product promotional communications on sites that are owned, controlled, created, influenced, or operated by, or on behalf of, the firm
- Responsible if the firm collaborates on or has editorial, preview, or review privilege over the content

## Factors in Determining Postmarketing Submission Requirements for Interactive Promotional Media

- Examples include sites that are under the control or influence of the firm, such as microblogs (e.g., Twitter), social networking sites (e.g., Facebook), and blogs



## Factors in Determining Postmarketing Submission Requirements for Interactive Promotional Media

- Under certain circumstances, a firm is responsible for promotion on third-party sites
  - Responsible if a firm has any control or influence on the third-party site
  - Responsible if a firm collaborates, or has editorial, preview, or review privilege
  - Responsible if a firm influences the placement of its promotion within the third-party site

## Factors in Determining Postmarketing Submission Requirements for Interactive Promotional Media

- A firm is not responsible if it only provides financial support (e.g., through an unrestricted educational grant) and has no control or influence on the third-party site

## Factors in Determining Postmarketing Submission Requirements for Interactive Promotional Media

- A firm is responsible for the content generated by an employee or agent who is acting on behalf of the firm to promote the firm's product
- FDA's regulation of prescription drug product promotion extends both to promotional activities that are carried out by the firm itself, and to promotion conducted on the firm's behalf

## Factors in Determining Postmarketing Submission Requirements for Interactive Promotional Media

- A firm generally is not responsible for UGC that is truly independent of the firm (i.e., is not produced by, or on behalf of, or prompted by the firm in any particular)
- FDA will not ordinarily view UGC on firm-owned or firm-controlled venues as promotional content on behalf of the firm as long as the user has no affiliation with the firm and the firm had no influence on the UGC

# Recommendations

- FDA recommends that a firm be transparent in disclosing its involvement on a site by clearly identifying the content and communications of its employees or agents acting on behalf of the firm
  - This could be achieved by inclusion of the firm's identifier (e.g., name or logo) as part of the communication

# Submission of Sites for Which a Firm is Responsible

- At the time of initial display, submit in its entirety all sites for which a firm is responsible on Form FDA 2253 or Form FDA 2301
  - Submit the comprehensive static product website with the addition of the interactive or real-time components
- Include annotations to describe the parts that are interactive and allow for real-time communications

## Submission of Sites for Which a Firm is Responsible

- Any subsequent changes should be annotated and resubmitted at the time of initial display (i.e., resubmission)
- Provide a cross-reference by noting the submission date of the most recent version of the site in the comments section of the form

# Submission of Sites for Which a Firm is Responsible

- After the initial submission or resubmission, if the site is non-restricted and remains unchanged other than displaying real-time information, the firm can submit a monthly updated listing of the site that does not include screenshots or other visual representations of the actual interactive or real-time communication



## Submission of Third-Party Sites in Which a Firm's Participation is Limited to Interactive Communications

- Submit the home page of the third-party site, along with the interactive page within the third-party site and the firm's first communication at the time of initial display

## Submission of Third-Party Sites in Which a Firm's Participation is Limited to Interactive Communications

- After the initial submission, if the firm remains an active participant on the third-party site, and that site is non-restricted, the firm can submit a monthly updated listing of the site that does not include screenshots or other visual representations of the actual interactive or real-time communication

# Recommendations for Monthly Updates for Non-Restricted Sites

- Once every month, submit an updated listing of all non-restricted sites for which firm is responsible or in which it remains an active participant and that include interactive or real-time communications
- Multiple sites and the corresponding documents can be submitted with a single Form FDA 2253 or Form FDA 2301

# Recommendations for Monthly Updates for Non-Restricted Sites

- Include a separate document for each site which includes:
  - Site name
  - URL
  - Date range
  - Cross-reference to the date of the most recent submission of the site

# Recommendations for Monthly Updates for Non-Restricted Sites

- Screenshots or other visual representations of the actual interactive or real-time communications need not be submitted with the monthly updates if the site is non-restricted

# Recommendations for Monthly Updates for Restricted Sites

- If a site has restricted access (e.g., is password protected or a subscription is required) submit all content related to the discussion to adequately provide context to facilitate the review
- Screenshots or other visual representations of the actual site, including the interactive or real-time communications, should be submitted monthly on Form FDA 2253 or Form FDA 2301



## **Draft Guidance for Industry:**

# *Internet/Social Media Platforms with Character Space Limitations – Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices*

***Jean-Ah Kang, Pharm.D.***

Office of Prescription Drug Promotion

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# Character Space Limitations Draft Guidance

Describes FDA's current thinking about how firms that choose to present benefit information should present both benefit and risk information within promotion on Internet/social media platforms with ***character*** space limitations

## Within scope of guidance

- Online microblog messaging (e.g., Twitter)
- Online paid search (e.g., Google/Yahoo "sponsored links")
- Future ***character-space-limited*** Internet/social media platforms (long-term applicability)

## Outside scope of guidance

- Product websites
- Webpages on social media networking platforms (e.g., individual product webpages on Facebook, Twitter, YouTube)
- Online web banners
- Responsive web design or other technology-specific presentations (e.g., mobile devices, tablets)





# Importance of This Draft Guidance

- Responds to stakeholder requests for clarification
  - In November 2009, FDA posed this issue as one of five main discussion topics at the Part 15 public hearing on Internet/social media promotion
- Advances FDA's mission in protecting public health
  - Regardless of the platform, truthful, accurate, and balanced product promotion best serves the public



## Overview of FDA's Policy

- Regardless of character space constraints that may be present on certain Internet/social media platforms, if a firm chooses to make a product benefit claim, the firm should also incorporate risk information within the same character-space-limited communication.
- The firm should also provide a mechanism to allow direct access to a more complete discussion of the risks associated with its product.

# Communication of Benefit Information

1. Benefit information should be accurate and non-misleading and reveal material facts within each individual character-space-limited communication (e.g., each individual message or tweet).
2. Benefit information should be accompanied by risk information within each individual character-space-limited communication.
3. If a firm concludes that adequate benefit and risk information, as well as other required information, cannot all be communicated within the same character-space-limited communication, then the firm should reconsider using that platform for the intended promotional message as it may not provide meaningful presentations of both benefit and risk—particularly for products with complex indications or extensive serious risks.

## “Twitter” Example 1A (Benefit Information)

- A firm is considering promotion of its prescription drug *NoFocus* on Twitter, which is limited to 140 character spaces per message or tweet.
- *NoFocus* is indicated for mild to moderate memory loss.
- Any benefit information that the firm communicates about *NoFocus* should be accurate and non-misleading and include material facts about the use of *NoFocus*, i.e., that it is indicated for **mild to moderate** memory loss.

NoFocus for mild to moderate memory loss [40/140]

## “Google” Example 2A (Benefit Information)

- A firm is considering promotion of its prescription drug *Headhertz* using Google’s Sitelink extensions (sponsored link promotion that contains character space limitations and specific formatting requirements, referred to as “Sitelinks”).
- *Headhertz* is indicated for severe headache associated with traumatic brain injury.
- If the sponsored link promotion contains benefit information about *Headhertz*, to be accurate and non-misleading, it should convey that *Headhertz* is indicated for **severe** headache **associated with traumatic brain injury**.

[Headhertz](#) [9/25]

[www.headhertz.com](http://www.headhertz.com) [17/35]

For severe headache from traumatic brain injury [47/70]



# Communication of Risk Information

1. Risk information should be presented together with benefit information within each individual character-space-limited communication (each individual message or tweet).
2. The content of risk information presented within each individual character-space-limited communication should, at a minimum, include the most serious risks associated with the product.



## Communication of Risk Information *(continued)*

3. A mechanism, such as a hyperlink, should also be provided within each individual character-space-limited communication to allow direct access to a more complete discussion of risk information about the product.
4. The prominence of risk information should be comparable to the benefit information within each character-space-limited communication, taking into consideration any formatting capabilities available on the specific Internet/social media platform.

## “Twitter” Example 1B (Risk Information)

- There are no boxed or other warnings and no known fatal or life-threatening risks included in the PI for *NoFocus*.
- The most serious precaution associated with *NoFocus* is that it may cause seizures in patients with a seizure disorder.

NoFocus for mild to moderate memory loss; may cause seizures in patients with a seizure disorder [www.nofocus.com/risk](http://www.nofocus.com/risk) [117/140]

- The firm includes a direct hyperlink to the “Important Safety Information” webpage (within the product website) that is devoted to providing comprehensive risk information about *NoFocus*.



## “Google” Example 2B (Risk Information)

- The PI for *Headhurtz* includes a boxed warning about the potential for brain swelling and warnings about a potentially fatal drug reaction and a drop in heart rate that may be life-threatening.

[Headhurtz](#) [9/25]

[www.headhurtz.com](http://www.headhurtz.com) [17/35]

For severe headache from traumatic brain injury [47/70]

[Boxed warning](#) [13/25]

Potential for brain swelling [28/35]

[Warning](#) [7/25]

Life-threatening drop in heart rate [35/35]

[Warning](#) [7/25]

Potentially fatal drug reaction [31/35]

[Risk information](#) [16/25]

Important safety information [28/35]

- Sitelinks 1-3 are direct hyperlinks to webpages about the specific risk listed; Sitelink 4 is a direct hyperlink to the “Important Safety Information” webpage within the product website.



# Inclusion of Other Product Information

- FDA does not intend to object to the following:
  - Communicating the established name directly to the right of, or directly below, the proprietary name within the character-space-limited communication
  - Substituting commonly recognized linguistic symbols for words
  - Using punctuation marks to help with the presentation of information
  - Denoting a chemical ingredient name with a scientific abbreviation

## “Twitter” Example 1C (Other Information)

- The FDA-approved name is *NoFocus (rememberine hydrochloride) Capsules*.
- *NoFocus* is available as 200mg capsules.

NoFocus (rememberine HCl) for mild to moderate memory loss-May cause seizures in patients with a seizure disorder [www.nofocus.com/risk](http://www.nofocus.com/risk) [133/140]

- At the top of the landing page, the firm again communicates the brand and established names together with the dosage form and quantitative information in direct conjunction as follows:
  - NoFocus (rememberine hydrochloride) 200 mg Capsules

## “Google” Example 2C (Other Information)

- The FDA-approved name is *Headhurtz (ouchafol) Tablets*.
- *Headhurtz* is available as 200mg tablets.

[Headhurtz \(ouchafol\)](#) [20/25]

[www.headhurtz.com](http://www.headhurtz.com) [17/35]

For severe headache from traumatic brain injury [47/70]

[Boxed warning](#) [13/25]

Potential for brain swelling [28/35]

[Warning](#) [7/25]

Life-threatening drop in heart rate [35/35]

[Warning](#) [7/25]

Potentially fatal drug reaction [31/35]

[Risk information](#) [16/25]

Important safety information [28/35]

- At the top of each landing page, the firm again communicates the brand and established names together with the dosage form and quantitative information in direct conjunction as follows:
  - Headhurtz (ouchafol) 200 mg Tablets



# Summary

FDA recommends that firms:

- First carefully consider the complexity of the indication and risk profiles for each of their products to determine whether a character-space-limited platform will enable meaningful presentations of both benefit and risk information.
- Then take the factors, recommendations, and hypothetical examples outlined in this draft guidance into account when developing benefit and risk presentations.



# Please submit your comments!

- ***Due date is Tuesday, September 16, 2014***
  - Submit comments online at [www.regulations.gov](http://www.regulations.gov) (docket #FDA-2014-D-0397)
  - Federal Register Notice with direct link for submitting comments <https://federalregister.gov/a/2014-14220>
- Link to draft guidance  
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM401087.pdf>



**Draft Guidance for Industry:**  
*Internet/Social Media Platforms:  
Correcting Independent Third-Party  
Misinformation About Prescription Drugs  
and Medical Devices*

***Julie Chronis, J.D.***

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# Correcting Misinformation Draft Guidance

Describes FDA's current recommendations to drug and device companies that voluntarily choose to respond to misinformation created or disseminated by independent third parties related to their FDA-regulated medical products on the Internet or through social media platforms.

## Within scope of guidance

- Communications that a firm is *not* responsible for fall within the scope of the guidance
- Third-party UGC on a third-party site
- Third-party UGC on a firm's own platform

## Outside scope of guidance

- A firm's own advertising or promotional labeling
- Adverse event reporting
- Corrective messages sent in response to a Warning Letter (e.g., DHCP letters)



# Importance of This Draft Guidance

- Responds to stakeholder requests for clarification
  - In November 2009, FDA posed this issue as one of five main discussion topics at the Part 15 public hearing on Internet/social media promotion
- Advances FDA's mission in protecting public health
  - Information generally available may be improved if firms correct misinformation
  - The public health is best served when information about FDA-regulated products is accurate, truthful, and not misleading



## Overview of FDA's Policy

- This draft guidance clarifies how firms can respond to *misinformation* about their drug or device products that was created or disseminated by third parties unaffiliated with the firm
- *Misinformation* - positive or negative incorrect representations or implications about a firm's product



# Overview of FDA's Policy

- The correction of misinformation is a voluntary activity
- If a firm corrects misinformation in a truthful and non-misleading manner per the guidance, FDA does not intend to object if *appropriate corrective information* does not satisfy otherwise applicable regulatory requirements regarding labeling or advertising (if any)

## Importance of *Responsibility*

- Firms must *not be responsible* for the communication containing the misinformation
  - Example: A firm discovers an unaffiliated blogger who is posting incorrect misinformation about the firm's product. The firm is not responsible for the misinformation and may voluntarily correct the misinformation if it chooses.

# “Appropriate corrective information”

- A firm may provide truthful and non-misleading corrective information
- To constitute appropriate corrective information, a firm’s communication should:
  - Be relevant and responsive to the misinformation;
  - Be limited and tailored to the misinformation;
  - Be non-promotional in nature, tone, and presentation;
  - Be accurate;
  - Be consistent with the FDA-required labeling for the product;
  - Be supported by sufficient evidence, including substantial evidence, when appropriate, for prescription drugs;
  - and...

## “Appropriate corrective information” (cont.)

- Either be posted in conjunction with the misinformation in the same area or forum (if posted directly to the forum by the firm), or should reference the misinformation and be intended to be posted in conjunction with the misinformation (if provided to the forum operator or author); and
  - Disclose that the person providing the corrective information is affiliated with the firm that manufactures, packs, or distributes the product.
- Additionally, FDA-required labeling should be included or provided in a readily accessible format
    - (e.g., non-promotional link that goes directly to the FDA-required labeling)



## Example of Appropriate Corrective Information

- Example: An independent third party writes an online post stating that one reason he likes taking a prescription drug (or using a device) is that it has no food restrictions, which is inconsistent with information from the required labeling regarding the need to avoid taking the drug with fatty foods (or to avoid using the device in a certain way). The firm decides to correct the misinformation according to this draft guidance. The firm's representative identifies herself as being affiliated with the firm and posts the corrective information from the required labeling. She also includes a direct link to the FDA-required labeling.

## Other Options for Correcting Misinformation

- It might not be possible due to technological limitations (e.g., a non-interactive webpage) for a firm to directly correct misinformation.
- Regardless of technological limitations -
  - Firms may contact the author of the misinformation and provide the information to author, request the misinformation be removed, or ask the author to allow comments to be posted
  - Firms may contact the site administrator and request the misinformation be removed or allow comments to be posted
  - Firms are not accountable if a third party declines to post corrective information or remove misinformation
- Firms may provide contact information for the firm (e.g. Medical Affairs)



## Other Options for Correcting Misinformation - Examples

- Example: A firm finds a webpage about its product that was written by an independent third party on an Internet-based, interactive, collaboratively edited encyclopedia. The firm may choose to contact the author of the webpage and provide corrective information to the author.
- Example: An independent third party posts a video on a video hosting website about a firm's product. It is not possible for viewers, such as a firm, to post comments about the video. The firm may contact the entity that administers the website and ask that entity to allow comments about the video to be posted so that the firm may post corrective information.

# Correcting a *Clearly Defined Portion* of a Forum

- A firm should
  - Describe the location or the nature of the information that was corrected
  - Define the portion of the forum it is correcting
  - Correct all the misinformation in the clearly defined portion
  - Provide a date the correction is made
  
- A firm should not
  - Choose to correct only misinformation that portrays its product in a negative light
  - Define a portion so it only has to respond to negative misinformation

# Correcting a Clearly Defined Portion of a Forum – Examples

- Example: A firm decides to correct misinformation posted by an independent third party who has commented on a blog that allows comments. The firm should correct each piece of misinformation in the particular comment to which it is responding. The firm should provide a statement that it is responding only to one particular comment along with the date the correction is provided. The firm is not expected to correct misinformation that appears in other comments.

# Correcting a Clearly Defined Portion of a Forum – Examples

- Example: A firm decides to correct misinformation posted on a blog that allows comments. The firm corrects misinformation in several blog postings that provide incorrect risk information associated with the product and makes clear it is only correcting those pieces of misinformation, but the firm does not address exaggerated efficacy claims in favor of the firm's product in other postings that appear to readers between the postings it is correcting. Even if the firm corrects the misinformation in the limited posts it chose, the firm's actions are not in accord with this guidance because it has intentionally selected only negative information about its product to correct while readily accessible and visible positive misinformation was not corrected.

# Communications That Fall Outside the Scope of This Draft Guidance

- Communications by a firm that are designed to correct misinformation should not go beyond the correction of misinformation or the communication will fall outside the scope of the guidance.
- Example: An independent third party downplays a labeled contraindication on an email distribution list. A firm provides the corrective information regarding the contraindication, and additionally provides information unrelated to the contraindication comparing the safety profile of its product to a competitor's product. The firm's communication goes beyond providing corrective information with respect to the third party's statements about the product's contraindication and, therefore, is not considered to be a correction of misinformation within the scope of this draft guidance.

# Consequences of Correcting Misinformation

- A firm does not have to continue to monitor a website or communication once it corrects misinformation.
- Record keeping
  - Firms do not have to submit appropriate corrective information to FDA
  - However, FDA recommends firms keep records to assist in responding to questions the Agency may have



# Please submit your comments!

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  - Submit comments online at [www.regulations.gov](http://www.regulations.gov) (docket #FDA-2014-D-0447)
  - Federal Register Notice with direct link for submitting comments <https://federalregister.gov/a/2014-14221>
- Link to draft guidance  
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM401079.pdf>



# Questions?





# Thank you for joining us.

For more information on OPDP topics, please visit:

<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm397791.htm>