OPDP Update on Oversight of Prescription Drug Promotion

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November 3, 2014

Topics

- Policy and Guidance Development
- Enforcement Overview and Analysis

Guidance Development

- Six draft guidances published since last year's Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum
- Follows Good Guidance Practices (GGPs)
  - Comments submitted to docket of draft guidances
  - Comments are reviewed and considered and may lead to revisions to draft guidance as it is being finalized and published as a final or draft

Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling

- Disclosure of product name is important for the proper identification and the safe and effective use of the product
- Responsive to questions and requests for clarification after publication of previous guidance

Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling

- Use of established name on page or spread
  - Established name accompanies the proprietary name at least once per page or spread where the proprietary name most prominently appear on the page or spread

- Use of established name in running text or columns
  - If established name is not featured (e.g. as headline) but is only part of the running text, the established name accompanies the proprietary name at least once in the running text
  - If the running text spans more than one page or spread, established name accompanies the proprietary name at least once per page of spread

Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling

- Use of established name in audio portion of a/v promotional labeling and a/v broadcast ads (i.e., TV ads)
  - For superimposed text (supers) that are equivalent to headline or tagline, established name need not be audio if established name is in direct conjunction with the most prominent display of the proprietary name in super

- Use of established name on Web pages or electronic screens
  - Established name accompanies the proprietary name at least once per Web page or screen where the proprietary name most prominently appears on the Web page or screen
  - The most prominent display of the proprietary name is generally near the top of the relevant Web page or screen on most electronic devices

Distributing Scientific and Medical Publications on Unapproved New Uses – Recommended Practices

- Previous guidance addressed recommended practices for firms when they distribute certain scientific and medical publications that discuss unapproved new uses (off-label)
  - Scientific and medical journal articles
  - Reference texts
- Questions and comments received
  - Suggestions for more clarity about the distinction between practices for distribution of scientific/medical journal articles and reference texts
  - Suggestions to include clinical practice guidelines

Distributing Scientific and Medical Publications on Unapproved New Uses – Recommended Practices

- Responds to stakeholder comments by revising guidance
- Clarifies position on firms' distribution of reference texts
  - Based on differences between journal articles and reference texts
  - Separated as a section within draft guidance
- Adds new section on clinical practice guidelines

Distributing Scientific and Medical Publications on the Safety of Approved Drugs and Licensed Biological Products- Recommended Practices

- Focuses on distribution of scientific or medical journal articles that discuss new risk information for approved uses of approved drugs and biological products
- Addresses questions from our stakeholders
  - Regarding FDA's position on firms' dissemination of new scientific or medical information about the safety of approved uses of approved drugs
    - Independent of information on unapproved new uses

Distributing Scientific and Medical Publications on the Safety of Approved Drugs and Licensed Biological Products- Recommended Practices

- Safety profile of a drug evolves throughout its lifecycle as the extent of exposure to the product increases
- Important that healthcare professionals receive new risk information
- Nothing in draft guidance is intended to change a firm's existing obligation under the FD&C Act, PHS Act, and implementing regulations to update its approved labeling, to accurately reflect what is known about the safety profile of the drug, to ensure that the labeling is not false or misleading

Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics

- Factors taken into consideration to determine if product communications using interactive technologies are subject to FDA's postmarketing submission requirements
- FDA's recommendations for submitting interactive promotional materials

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
  - 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

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
  - 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

- After the initial submission, 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

- 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

Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices

Describes FDA's current thinking about how firms that voluntarily choose to correct misinformation related to their products should respond when that misinformation is created or disseminated by independent third parties on Internet/social media platforms

Within scope of guidance

- Communications that a firm is *not* responsible for
  - User-generated content (UGC) on a third-party site
  - UGC on a firm's own forum

Outside scope of guidance

- Communications that a firm *is* responsible for
  - A firm's own advertising or promotional labeling
- Adverse event reporting

"Appropriate corrective information"

- Relevant and responsive to the misinformation
- Limited and tailored to the misinformation
- Non-promotional in nature, tone, and presentation
- Accurate
- Consistent with the FDA approved labeling
- Supported by sufficient evidence
- Posted in conjunction with the misinformation
- Disclose that the person providing the corrective information is affiliated with the firm

Correcting a *Clearly Defined Portion* of a Forum

- A firm should
  - Describe the location or the nature of the misinformation 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

Other Options for Correcting Misinformation

- Provide contact information for the firm
- Contact the author of the misinformation
  - Provide corrective information to the author
  - Request the misinformation be removed
  - Ask the author to allow comments to be posted
- Contact the site administrator
  - Request the misinformation be removed
  - Ask the site administrator to allow comments to be posted

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

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, YouTube)
- Online web banners

Communication of Benefit Information

- Be accurate and non-misleading and reveal material facts within each individual message
- Be accompanied by risk information within each individual message

Communication of Risk Information

- Be presented together with benefit information within each individual message
- Include the most serious risks associated with the product
- Provide a mechanism, such as a hyperlink, to allow direct access to a more complete discussion of risk information about the product
- Have a prominence comparable to the benefit information, taking into consideration any formatting capabilities

Enforcement

Surveillance and Monitoring

- Disseminated materials submitted to FDA
  - Post-marketing submission requirements (Form FDA 2253)
- Conference attendance
- Complaints
- Healthcare Professional Outreach Initiative
  - Bad Ad Program
    - CE program for healthcare professionals released in October 2013

Risk Based Enforcement Approach

- FDA's allocation of resources and priorities based on impact on public health
  - FDA targets the promotional campaigns that have potential to harm patients the most
- High priority includes
  - Newly approved products
  - Products with significant risks
  - Products cited for violations in the past
  - Products cited in complaints
  - Products promoted with far reaching campaigns

Most Common Violations Cited in Regulatory Letters from January 2013 to Present

- Omission and minimization of risk information
- Unsubstantiated superiority claims
- Overstatement of efficacy claims

OPDP Web Resources

- OPDP home page
  - http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm090142.htm
- OPDP organization listing
  - http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm154886.htm
- OPDP guidances
  - http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm109905.htm#Guidances
- Warning and untitled letters
  - www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/default.htm

OPDP Contact Information

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Thank You!