FDA Update on Oversight of Prescription Drug Promotion

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Food and Drug Administration
January 28, 2014
Topics

• Operations and Reorganization Update
• Enforcement Overview and Analysis
• Policy and Guidance Development
Office of Prescription Drug Promotion (OPDP)

- Formerly known as the Division of Drug Marketing, Advertising, and Communications (DDMAC)
- September 2011 - DDMAC was reorganized and elevated to an office structure (OPDP) which consists of:
  - Immediate Office
  - Two Divisions
- OPDP alignment based on functional areas
  - Review functions
  - Policy and support functions
Office of Prescription Drug Promotion

• Immediate Office
  – Office Director (Thomas Abrams)
  – Associate Office Director (Mark Askine)
    • Review Functions
      – Two Divisions
  – Associate Office Director (Marci Kiester)
    • Policy and Support Functions
      – Regulatory Counsel Team
      – Social Science Research Team
      – Project Management Team
Office of Prescription Drug Promotion

- Changes in Divisions made March 2013
  - Strive for continuous improvement and increases in efficiency
  - Reviewed and analyzed workload and review processes with following goals
    - Increase efficiency, improve work distribution, and eliminate redundancy
  - Concluded that structure that integrates the review of HCP directed and DTC promotion across the two divisions would meet these goals
  - Each Division oversees different therapeutic classes of drugs for even work distribution
  - Decision to restructure to allow for more effective review processes reflects our commitment to continue to provide close oversight of DTC promotion
Office of Prescription Drug Promotion

• Division Names are Pending Approval
  – Division I
    • Division of Advertising and Promotion Review I
      – Andrew Haffer, Acting Director
      – Lisa Hubbard, Acting Deputy Director
      – 4 Review Teams and Team Leaders
  – Division II
    • Division of Advertising and Promotion Review II
      – Robert Dean, Director
      – Michael Sauers, Deputy Director
      – 4 Review Teams and Team Leaders
Top Priorities of OPDP

• Policy and guidance development
• Labeling reviews
• Core launch reviews and TV ad reviews
• Enforcement
• Training and communications

Note all are top priorities and not in any rank order
Voluntary Compliance

• Overall promotional materials appear to be improving
  – Work and efforts by FDA and industry
  – Important for the public, industry, and FDA

• Need to continue our work
  – Certain promotional proposals and suggestions are also concerning
  – Other promotional materials and activities are violative
Enforcement
Surveillance

• Disseminated materials submitted to FDA
  – Post-marketing reporting requirements (Form FDA 2253)
• Conference attendance
• Complaints
• Healthcare Professional Outreach Initiative
  – Bad Ad Program
• Broad surveillance of materials
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 in 2013

• Omission and minimization of risk information
• Misleading superiority claims
• Misleading efficacy claims
Guidance Development Plans

• Internet/social media promotion
  – Continue development of internet/social media guidance concepts

• Revising current draft guidances
  – Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements
  – Presenting Risk Information in Prescription Drug and Medical Device Promotion

• Exploring and discussing other areas of interest
  – Clinical practice guidelines
  – Health care economic information/formularies
  – Comparative claims
  – Scientific exchange
Recently Issued Draft Guidances

• *Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling*  
  – Published November 2013

• *Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics*  
  – Published January 2014
Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling

- Responsive to questions and requests for clarification after issuance of previous guidance

- Disclosure of product name is important for the proper identification and the safe and effective use of the product
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
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
Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics

• Factors include
  – (1) Firm is responsible for product promotional communications on sites that are owned, controlled, created, influenced, or operated by, or on behalf of, the firm
  – (2) Under certain circumstances, a firm is responsible for promotion on third-party sites
    • Responsible if firm has any control or influence on the third-party site
    • Not responsible if only providing financial support (e.g., unrestricted educational grant and no control/influence etc)
Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics

• Factors include
  – (3) Firm is responsible for content generated by an employee or agent who is acting on behalf of the firm to promote the firm’s product
    • Recommend that firm be transparent in disclosing its involvement on a site by clearly identifying the user generated content and communications
Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics

• Recommendations to illustrate possible approaches for submitting interactive promotional media
  – Sites that firm is responsible for
    • At the time of initial display, submit in its entirety all sites for which firm is responsible
    • Include comprehensive static product website with the addition of the interactive or real-time components
    • If non-restricted site, and site remains unchanged other than displaying real-time information, firm can submit an updated listing of the site
Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics

• Recommendations to illustrate possible approaches
  – For third-party sites on which a firm’s participation is limited to interactive or real-time 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
    • If non-restricted site, and firm remains an active participant on the third-party site, firm can submit an updated listing of the site
Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics

• Updated listing of non-restricted sites for which the firm is responsible for or in which it remains an active participant and that include interactive or real-time communications
  – Submit Form FDA 2253 or 2301 for these sites monthly
  – Multiple sites can be submitted with a single Form FDA 2253 or 2301
    • Each site should have a separate document which includes site name, URL, and date range, as well as a cross-referenced to the date of the most recent submission of the site
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
OPDP Contact Information

• Telephone Number
  – 301-796-1200

• Fax Numbers
  – 301-847-8444
  – 301-847-8445

• Submission Address
  – Food and Drug Administration
    Center for Drug Evaluation and Research
    Office of Prescription Drug Promotion
    5901-B Ammendale Road
    Beltsville, MD 20705-1266