OPDP Update on Oversight of Prescription Drug Promotion

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Topics

- Operations and Reorganization Update
- Policy and Guidance Development
- Enforcement Overview and Analysis

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

Guidance Development Plans

- 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
  - Health care economic information/formularies
  - Medical practice guidelines
  - Comparative claims
  - Scientific exchange
    - FR Notice seeking comments
- Working on Internet/social media promotion

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
- Broad surveillance of materials
- Healthcare Professional Outreach Initiative
  - Bad Ad Program

The Bad Ad Program

- FDA-sponsored outreach program designed to increase awareness of healthcare professionals (HCPs) about the role they can play in helping FDA ensure that prescription drug advertising and promotion is truthful and not misleading
- When HCPs recognize misleading drug promotion, they can help put a stop to it by reporting it to FDA:
  - Call
    - **855-RX-BadAd**
  - E-mail
    - **BadAd@fda.gov**

The Bad Ad Program Highlights

- Developed educational materials for healthcare professionals
- Extensive outreach
  - Staffed exhibits at medical conferences
  - Presented at U.S. teaching hospitals
  - Participated in webcast for FDA's Expert Commentary Series on Medscape
  - Hosted live Bad Ad webinar for medical and pharmacy professionals
- Running journal ad campaign
- Pursuing opportunities to enhance student education (medical/pharmacy/nursing)
- Developing web-based continuing education program for the nation's healthcare professionals

Risk-Based Enforcement Approach

- Focus on the impact on public health including:
  - 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 from January 2012 to September 2013

- Omission and minimization of risk information
- Misleading superiority claims
- Misleading 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

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