Enforcement and Policy Update from DDMAC

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Food and Drug Administration
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Topics

- Voluntary compliance
- Enforcement update
- Organizational update
- Policy update

Goal and Objectives

- Goal
  - To protect and promote public health
- Objectives
  - Ensure that RX drug promotion is not false or misleading
  - Ensure that balanced picture of drug is conveyed
  - Aid in the communication of more useful information about drugs and diseases to the American public

Voluntary Compliance

- Objectives
  - Compliant promotion and not have violative promotion in the marketplace.
  - High quality and educational promotion
- FDA would prefer to prevent misleading messages than reacting to them
- Public health benefits
  - Not exposed to misleading messages
  - Instead consumers and HCPs should have good and balanced information
- Industry benefits
  - Provides good information to public
  - Better image
  - Avoid regulatory actions
  - No interruption in promotional campaigns

Efforts to Increase Voluntary Compliance

- FDA's Efforts
  - Guidance documents
  - Requests for comments
  - Educational and outreach efforts
- Industry's Efforts
- FDA's comprehensive surveillance and enforcement program

Enforcement

Surveillance

- Disseminated materials submitted to FDA
  - Post-marketing reporting requirements (Form 2253)
- Conference attendance
- Complaints
- Broad surveillance of materials used
  - Numerous, evolving and creative ways of promoting prescription drugs by industry, especially on the Internet
- Health Care Professional Outreach Initiative

Promotional Vehicles Cited Include

- Traditional
  - Journal and magazine ads
  - TV ads
  - Sales aids
  - Sales reps' activities
  - Promotion in commercial exhibit halls
  - Medical convention post meeting news ad
  - Mailers to healthcare professionals
- Evolving Technology
  - Facebook
  - Consumer DVDs
  - Webcast videos
  - Promotional videos on cnn.com and youtube.com
  - Online banners
  - Sponsored links
  - Patient in-house events

Risk Based Enforcement Approach

- Impact on public health
- 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

Common Violations

- Omission and minimization of risk information
- Unsubstantiated claims of efficacy or safety
- Unsubstantiated comparative claims
- Promotion of unapproved uses of drugs

Enforcement Options

- Untitled letters (notice of violation or NOV)
- Warning Letters
- Injunctions/consent decrees
- Seizures
- Civil Monetary Penalties for DTC ads
- Work with other government agencies
  - Department of Justice
  - Office of Inspector General
  - States AG's

Enforcement Focus

- FDA Enforcement Initiative announced by Commissioner
- Streamline processes for untitled and warning letters
- Number of untitled and warning letters significantly increasing
  - 2008: 21
  - 2009: 41
  - 2010 YTD (Jan-Sept): 45
- Risk based enforcement approach
- Follow-up on enforcement actions

Health Care Professional Outreach (BadAd Program)

- FDA seeks to collaborate with HCPs to address misleading promotion
- Two-fold purpose of program
  - Increase awareness of HCPs about importance of preventing misleading promotion
  - Inform HCPs on how to identify and report these activities
- Addresses difficult to access promotion
  - “Detailing” occurs in setting such as offices, hospitals, and dinner meetings
- Positive response from medical groups and healthcare professionals

The Division of Drug Marketing, Advertising, and Communications

Director's Office

Director, Thomas Abrams
Deputy Director, vacancy
Associate Director, Mark Askine
Associate Director of Operations, Marci Kiester
Management Advisor, Catherine Gray
Management Advisor, Robert Dean
Special Assistant, Jean-Ah Kang
Program Specialist, Becki Vogt

Regulatory Counsel Team Leader, Sangeeta Vaswani
Regulatory Counsel, Marissa Chaet Brykman
Regulatory Counsel, Julie Burger
Regulatory Counsel, Bryant Godfrey
Regulatory Counsel, Ernest Voyard
IT Specialist, Michael Wade

Evidence Review & Division Support, Elaine Cunningham
Regulatory Project Manager, Wayne Amchin
Training & Support, Barbara Chong
TIA, Janet Daly
TIA, Sharon Smith

Professional Review Group I	**Professional Review Group II**	**Professional Review Group III**	**Professional Review Group IV**	**Direct-To-Consumer Review Group I**	**Direct-To-Consumer Review Group II**	**Direct-To-Consumer Review Group III**	**Direct-To-Consumer Review Group IV**
Leader Andrew Haffer (acting)	Leader Karen Rulli (acting)	Leader Lisa Hubbard	Leader Sheila Ryan	Leader Michael Sauers	Leader Aline Moukhtara (acting)	Leader Shefali Doshi (acting)	Leader Amy Toscano (acting)
Neurology (Quynh-Van Tran)	Oncology Drugs: Solid tumors (Keith Olin)	Pulmonary, Allergy, Rheumatology (Roberta Szydlo)	Cardiovascular and Renal (Emily Baker)	Reproductive (Carrie Newcomer)	Neurology (Sharon Watson, Beth Carr)	Anesthetics, Analgesics, Rheumatology (Twyla Thompson)	Cardiovascular and Renal (Zarna Patel)
Oncology Biologics (Carole Broadnax)	Oncology Drugs: Hematologic Cancers (Adam George, Nisha Patel)	Analgesics, Anesthetics (Mathilda Fienkeng)	Anti-Infectives, Ophthalmology, Special Pathogens, Transplant (Christine Corser)	Psychiatry (Susannah Hubert)	Pulmonary, Allergy (Robyn Tyler)	Gastroenterology (Cindy Collins)	Oncology Drugs (Stephanie Victor)
Reproductive, Urology (Janice Maniwang)	Hematology, Medical Imaging (James Dvorsky)	Metabolism and Endocrinology (Samuel Skariah)	Antivirals (Lynn Panholzer)	Urology (Osteo, Other), Antivirals, Special Pathogens, Transplant (Michelle Safarik)	Urology (Vacancy)	Oncology Biologics (Vacancy)	Hematology, Medical Imaging, Anti-Infectives, Ophthalmology (JuWon Lee)
Psychiatry (Jessica Derenick)		Gastroenterology (Kathleen Klemm)	Dermatology, Dental (Vacancy)	Dermatology, Dental (Sheetal Patel)	**Research Team** (Kathryn Aikin, Amie O'Donoghue, Helen Sullivan)	Metabolism and Endocrinology (Kendra Jones)	(Vacancy)

Future is Office Structure

- From Division to Office structure
  - Immediate Office
  - 2 Divisions
    - Healthcare Professional directed materials
    - Consumer directed materials
- Enhance efforts for voluntary compliance
- Strengthen enforcement
- Decrease advisory response times
- Increase Guidance development

FDA DTC FDAAA Update

- FDA implementation of the Direct-to-Consumer Advertisement provisions of the Food and Drug Amendments Act of 2007 (FDAAA)
  - Report to Congress on DTC Advertising issued April 2010
  - Clear, conspicuous and neutral proposed rule published March 2010

Report on DTC Advertising

- Agency must report to Congress on DTC advertising's ability to communicate to population subsets, including the elderly, children, and racial and ethnic minority communities
- Advisory Committee on Risk Communication has to advise on this report – met with them on May 15, 2008

Report on DTC Advertising

- Report was sent to Congress in April
  - available at: http://www.fda.gov/downloads/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FoodandDrugAdministrationAmendmentsActof2007/FDAAAImplementationChart/UCM214303.pdf

Broadcast ads – major statement

- Section 502(n) of FDCA, as modified by FDAAA, requires that the "major statement" of risk information in consumer-directed prescription human drug TV & radio ads be presented in a "clear, conspicuous, and neutral manner"
  - Per FDAAA, FDA shall by regulation establish standards for determining whether a major statement meets this requirement

Proposed Rule

- FDA issued the proposed clear, conspicuous, and neutral manner rule on March 29, 2010
  - Direct-to-Consumer Prescription Drug Advertisements; Presentation of the Major Statement in Television and Radio Advertisements in a Clear, Conspicuous, and Neutral Manner
  - Docket No. **FDA-2009-N-0582**
    - the full text of the proposed rule can be viewed on www.regulations.gov

FDA's Proposed Standards

- A major statement is clear, conspicuous, and neutral if:
  - Information is presented in language that is readily understandable by consumers;
  - Audio information is understandable in terms of the volume, articulation, and pacing used;
  - Textual information is placed appropriately and is presented against a contrasting background for sufficient duration and in a size and style of font that allows the information to be read easily; and
  - The advertisement does not include distracting representations (including statements, text, images, or sounds or any combination thereof) that detract from the communication of the major statement

Additional Consideration

- FDA considered adding a 5th standard that would require that the major statement in TV ads be included in **both** the audio and visual parts of the presentation
  - This is similar to one of the FTC standards for clear and conspicuous disclosures in television commercials
  - Research has shown that presenting information in such a dual-mode manner increases the comprehension of that information

FDA's Proposed Standards

- FDA believes there is more than one way to achieve the proposed standards in a television or radio ad
- FDA intends to continue to consider the variety of techniques sponsors may use to appropriately convey required risk information in prescription drug ads
- Sponsor retain the flexibility to be creative in designing their ads, as long as the standards in any final rule are complied with

Guidance Development

- Presentation of Risk Information Draft Guidance issued in May 2009
- Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements (Brief Summary)
- Promotion using Social Media Tools
- TV Ads – FDAAA DTC TV Pre-Review Program
- Exploring other areas such as comparative claims in promotion

Guidance Development Planning

- Interested in what our stakeholders believe are important areas to address
- Origin of policy development for social media on the internet
- Let us know what you feel is important and why

Web Addresses

- DDMAC webpage
  - www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm
- DDMAC organization listing
  - www.fda.gov/AboutFDA/CentersOffices/CDER/ucm154886.htm
- Warning and untitled letters
  - www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/default.htm
- Guidances
  - www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm064956.htm

DDMAC Contact Information

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