Direct-to-Consumer Promotion: FDA Update

Marci Kiester, PharmD
DDMAC, CDER
April 17, 2009
Direct-to-Consumer Promotion: FDA Update

- Annual Update on DDMAC Organizational Structure and Submission Totals
- DTC Enforcements
# The Division of Drug Marketing, Advertising, and Communications

**01/26/09**

## Director's Office
- **Director**, Thomas Abrams
- **Deputy Director**, Kristin Davis
- **Associate Director**, Mark Askine
- **Special Assistant**, Jean-Ah Kang
- **Program Specialist**, Becki Vogt

## Professional Review Group I
- **Leader**, Jialynn Wang
  - Neurology/Psychiatry (Amy Toscano)
  - Cardiovascular & Renal (Lisa Hubbard)
  - Reproductive & Urology (Janice Maniwang)
  - Medical Imaging & Hematology (Michelle Safarik)

## Professional Review Group II
- **Leader**, Catherine Gray
  - Oncology Drugs (JuWon Lee, Keith Olin, Karen Rulli)
  - Dermatology & Dental (Andrew Haffer)

## Professional Review Group III
- **Acting Leader**, Sangeeta Vaswani
  - Pulmonary & Allergy (Jessica Adams)
  - Analgesics, Anesthetics, & Rheumatology (Mathilda Fienkeng)
  - Metabolism & Endocrinology (Samuel Skariah)
  - Gastroenterology, Special Pathogens & Transplant (Kathleen Klemm)

## Professional Review Group IV
- **Leader**, Sheila Ryan
  - Anti-Infectives & Ophthalmology (Beth Carr)
  - Antivirals (Lynn Panholzer)
  - Oncology Biologics (Carole Broadnax, Jeffrey Trunzo)

## Direct-To-Consumer Review Group I
- **Leader**, Robert Dean
  - Oncology Drugs, Oncology Biologics (Beverly Bowers, Stephanie Victor)
  - Metabolic/Endocrine, Analgesics/Anesthetics Rheumatology (Kendra Jones, Michael Sauers)
  - Derm/Dental and GI, Pulmonary/Allergy (Shefali Doshi, Robyn Tyler)
  - Research Team (Kathryn Aikin, Amie O’Donoghue, Helen Sullivan)

## Direct-To-Consumer Review Group II
- **Leader**, Marci Kiester
  - Cardio-renal (Zarna Patel)
  - Psychiatry (Susannah Hubert)
  - Neurology, Anti-Infectives, Ophthalmology, Special Pathogens, Transplant (Sharon Watson, Twyla Thompson)
  - Antivirals (Aline Moukhtara)
  - Reproductive, Urology, Medical Imaging, Hematology, (Cynthia Collins, Carrie Newcomer)

### Regulatory Counsel
- Marissa Chaet

### Regulatory Counsel (Vacancy)

### IT Specialist
- Michael Wade

### Labeling
- Iris Masucci

### Training & Support
- Barbara Chong

### Evidence Review & Division Support
- Elaine Cunningham

### Project Manager
- Wayne Amchin
- Paul Loebach

### TIA
- Sharon Smith
- Vacancy
DTC Review Group Dockets

Direct-to-Consumer Review Group I (Robert Dean)
○ Oncology Drugs, Oncology Biologics (Beverly Bowers, Stephanie Victor)
○ Metabolic/Endocrine, Analgesics/Anesthetics, Rheumatology (Kendra Jones, Michael Sauers)
○ Derm/Dental and GI, Pulmonary/Allergy (Shefali Doshi, Robyn Tyler)
○ Research Team (Kathryn Aikin, Amie O’Donoghue, Helen Sullivan)

Direct-to-Consumer Review Group II (Marci Kiester)
○ Cardio-renal (Zarna Patel)
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# of Broadcast Ads Submitted
2003 - 2008

Proposed | Disseminated | Total
--- | --- | ---
2003: 163 | 311 | 474
2004: 142 | 441 | 583
2005: 146 | 337 | 483
2006: 89 | 327 | 416
2007: 89 | 388 | 477
2008: 97 | 368 | 474
DTC Enforcements

- Adderall XR
- Yaz
- Avodart
- Treximet
- Sponsored links
Adderall XR Warning Letter

- Video testimonial featuring Ty Pennington posted on youtube.com by Shire Development Inc (Shire) for Adderall XR
- Shire acknowledged its involvement in the development and dissemination of the video
Adderall XR Warning Letter

- Overstatement of Efficacy
  - Ty claims “Now once I got on medication it’s just amazing the transformation I made. I – It literally changed my life, and gave me the confidence to achieve my goals . . . . But the medicines like Adderall XR, it’s truly a transformation . . . . It’s not easy to communicate with people, including your own family. So you become kind of alienated. You feel like you’re different, and you don’t really fit in. . . . . Proper treatment has truly changed my life and made an amazing difference.”
Adderall XR Warning Letter

- Omission of Risk Information
  - Video presents numerous efficacy claims but entirely omits risk information

- Failure to Submit Under Form 2253
Yaz Warning Letter

- Two TV ads
- Broadening of Indication
  - Premenstrual Dysphoric Disorder (PMDD)
    - Misleadingly suggest that Yaz is appropriate for treating women with PMS
    - Nowhere do the ads use the full phrase “premenstrual dysphoric disorder”
    - Omit material limitation that “Yaz has not been evaluated for the treatment of premenstrual syndrome (PMS)”
  - Acne
    - Fails to adequately convey that Yaz is only indicated for the treatment of “moderate acne vulgaris”
Yaz Warning Letter

- **Overstatement of Efficacy**
  - **PMDD**
    - TV ad “Balloons” misleadingly suggests that treatment with Yaz will allow women to say “good-bye” to their symptoms, when such an elimination has not been demonstrated by substantial evidence or substantial clinical experience
  
  - **Acne**
    - Overwhelming impression conveyed by the TV ads is that treatment with Yaz results in clear, acne-free skin for those women suffering from acne when this has not been demonstrated by substantial evidence or substantial clinical experience
Yaz Warning Letter

- Minimization of Risk
  - Major statement minimized by distracting visuals, numerous scene changes, and other competing modalities such as the background music which combine to interfere with the presentation of the risk information
Date: 02.29.07
Agency: McCann Erickson
Client: GlaxoSmithKline
Product: AVODART
Title: "Planetarium"
ISCI: AVVO-78R0
Length: :60
Audio: Stereo
TV ad entitled “Planetarium”

Misleading Comparative Claims
- “So when my doctor said that my going and going could get worse because my prostate was growing I said ‘How can we shrink it?’”
- “He said ‘Avodart.’”
- “Avodart is different because over time it actually shrinks the prostate, so I go less often. Other medicines, they don’t treat the cause, because they don’t shrink the prostate.”
Avodart Untitled Letter

- Overstatement of Efficacy
  - Graphic images and verbal statements overstate the efficacy of Avodart therapy with respect to the results one can expect with Avodart.
  - Visual of the planet shrinking in size represents a reduction in prostate volume that is much greater than the reduction actually achieved with Avodart therapy in clinical trials.
Five online banners for Treximet

- Banners present efficacy claims prominently, utilizing techniques that are designed to emphasize this information, but relegate the risk information to a small, scrolling portion of the banner that is likely to be ignored by consumers.
Sponsored Link Untitled Letters

- Issued 14 untitled letters to 14 different companies regarding sponsored links on internet search engines
  - Letters covered 48 drugs
  - 19 of the products carry Boxed Warnings
- Violations included:
  - Broadening or inadequately disclosing the actual FDA-approved use of the drugs
  - Overstating the drugs benefits
  - Not providing any risk information
  - Failing to use the drug’s established name
Sponsored Link Untitled Letters

- In situations where we notice common problems across a therapeutic area’s promotion or across a certain promotional channel or vehicle, we may issue multiple letters simultaneously to maintain a level playing field.
- We are concerned from a public health perspective whenever promotion undermines the safe use of a drug by minimizing the risks associated with the product or by failing to appropriately communicate its approved uses.
Tips for How to Submit to DDMAC

- Consult DDMAC’s website prior to submitting materials (www.fda.gov/cder/ddmac)
- For time sensitive materials, please confirm receipt of the submission to DDMAC with a phone call to the project manager or appropriate reviewer (301-796-1200)
Contact Information

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  Group Leader
  Division of Drug Marketing, Advertising, and Communications
  301-796-1200