DDMAC

Division of Drug Marketing, Advertising, and Communications

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Regulatory Review Officer
February 26, 2009
Presentation Overview

- Mission
- Organizational structure
- Regulatory authority
- Operational role
- Advertising and promotion
- Examples of enforcement actions
DDMAC’s Mission

Protect the public health by assuring prescription drug information is truthful, balanced, and accurately communicated.

To guard against false and misleading advertising and promotion through comprehensive surveillance, enforcement, and educational programs.
# The Division of Drug Marketing, Advertising, and Communications

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

## Regulatory Support
- Regulatory Counsel, Marissa Chaet
- Regulatory Counsel, (Vacancy)
- Regulatory Counsel, (Vacancy)
- IT Specialist, Michael Wade
- Labeling, Iris Masucci
- Training & Support, Barbara Chong
- Evidence Review & Division Support, Elaine Cunningham
- Project Manager, Wayne Amchin
- Project Manager, Paul Loebach
- TIA, Sharon Smith
- TIA, (Vacancy)

## 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 Authority

- Federal Food, Drug and Cosmetic Act
  - Prescription drug promotion must...
    - Not be false or misleading
    - Have fair balance
    - Be consistent with the approved product labeling, or the package insert (PI)
    - Only include claims substantiated by adequate and well-controlled clinical studies
Regulatory Authority

Code of Federal Regulations (CFR)

- 202.1 - Prescription Drug Advertising
- 312.7 - Preapproval Promotion
- 314.550 - Subpart H, Accelerated Approval for Drugs
- 601.40 - Subpart E, Accelerated Approval for Biologics
Regulatory Authority

Post-Approval Regulations located in 21 CFR 314.81(b)(3):

- Require the submission of all promotional materials at the time of initial dissemination or publication
- Must include Form FDA 2253 and current PI
- DDMAC receives >70K submissions per year
- DDMAC does not generally “pre-clear” promotional materials
DDMAC’s Role

- Advice to industry/within FDA
- Surveillance and enforcement
- Guidances and policy development
- Research
Advice to Industry

- Provide comments on DRAFT promotional materials (VOLUNTARY in most cases)
  - Launch materials for new drugs or new indications
  - Direct-to-consumer (DTC) broadcast ads
  - Non-launch materials

- Pre-submission required for certain drugs
  (e.g., Subpart H/Subpart E “accelerated approval”)
Advice within FDA

Provide consultation on:

- Draft labeling
- Cartons and product labels
- Medication Guides
- Patient Package Inserts (PPIs)
- Dear Healthcare Provider letters
- Pharmacoeconomics, health-related patient-reported outcome protocols
Surveillance

- Review materials submitted to DDMAC at the time of initial dissemination (Form 2253)

- Conferences

- Complaints
  - Healthcare professionals
  - Consumers
  - Competitors
Enforcement

- Untitled letters (Notice of Violation/NOV)
- Warning letters
- Injunction/consent decree
- Seizures
- Criminal action
Categories of Promotional Materials

**Labeling**
- Audio, video, or printed matter (e.g., brochures, booklets, mailing pieces, exhibits, slides)
- Supplied or disseminated by the manufacturer, distributor, packer, or any party acting on behalf of the sponsor
- Accompanied by the approved product labeling

**Advertising**
- Advertisements in published journals, magazines, newspapers, and other periodicals
- Broadcast (e.g., TV, radio, telephone communication systems)
- Accompanied by a “Brief Summary” of the approved product label
Categories of Promotional Materials

- Help-Seeking
- Institutional
- Reminder
- Full Product

Cannot make any representations about a specific product - requires no balance
Help Seeking Ad

- May discuss a medical condition or disease state
- May include a company name
- May not include drug name
It may take a little courage to ask your doctor about erectile dysfunction. But everything worthwhile usually does.

When I was diagnosed with prostate cancer, my first concern was risking myself of the cancer. But I was also concerned about possible postoperative side effects, like erectile dysfunction (E.D.), often called impotence. So I asked my doctor about treatment options.

I’m speaking out now in the hope that men with E.D. will get proper treatment for a condition that affects millions of men and their partners.

Most E.D. cases are associated with physical conditions or events, like the prostate cancer surgery I underwent. The most common causes of E.D. include diabetes, high blood pressure, spinal cord injury, or surgery for the prostate or colon. E.D. can also be associated with smoking, alcohol abuse, or psychological conditions such as anxiety or stress.

The good news is that many effective treatments are available for E.D. But the important first step is to talk to your doctor. Together, you and your doctor can decide which treatment is best for you.

Now it’s up to you to get the treatment you need for E.D. My advice is to get a medical checkup. It’s the best way to get educated about E.D. and what can be done to treat it. It may take a little courage, but I’ve found that everything worthwhile usually does.

For more information about erectile dysfunction, please call 1-800-433-4215.

get EDUCATED ABOUT E.D.
Institutional

- Company name
- Area of research
- May not mention any drug names
Connecting minds is the key to faster innovation. Aventis Pharma.

Our challenge is life.

Aventis Pharma is one of the world's leading pharmaceutical companies. We are dedicated to converting scientific knowledge into innovative drugs for unmet medical needs. A key to this is the unique approach to research and development in our seamless drug innovation and approval organization — where we rapidly share new insights and build knowledge by leveraging our internal expertise with a large number of international strategic alliances. Cross-functional project teams work simultaneously around the globe to further reduce time to market of promising products. This ensures that innovative treatments get to patients faster. Our ability to harness new technologies and our research and development resources enable us to open new horizons for science-based medicine.

At Aventis Pharma, there is no higher priority than health and quality of life.
Reminder

- Must include proprietary and established name

- May call attention to drug name but may **NOT** contain any representation or suggestion relating to the advertised drug product

- May include dosage form, package contents, price, name of manufacturer, packer, distributor.

- Not permitted for drug with a Boxed Warning
Reminder Ad

Pulmicort RESPULES®
(budesonide inhalation suspension)

Learn more at PulmicortRespules.com
Full Product Claim Ads

- Include representation or suggestion relating to the advertised drug product

- Must include a balanced risk presentation ("fair balance")

- Must include the Brief Summary or PI
Oh no! I’ve lost an inch.

But I’ve found a way to fight osteoporosis with Actonel.

Wait a minute. Did you lose something? Like maybe an inch or so of height? You’re not the only one. After menopause, shrinking can be a sign of osteoporosis, the result of tiny fractures over time.

Little by little, osteoporosis can make your bones weak and brittle, even if you take calcium every day.

That’s how fractures can happen!

But Actonel once-a-week helps protect your bones from osteoporosis. It won’t get back your lost inch. But it will help you fight fracture.

How do your bones measure up? Get more information at Actonel.com and ask your doctor if Actonel is right for you.

Actonel is a prescription medication to treat and prevent postmenopausal osteoporosis. Some risk factors for osteoporosis include Caucasian or Asian race, family history, small frame or smoking.

You should not take Actonel if you have low blood calcium, have severe kidney disease, or cannot sit or stand for 30 minutes. Stop taking Actonel and tell your doctor if you experience difficulty or painful swallowing, chest pain, or severe or continuing heartburn, as these may be signs of serious upper digestive problems. Side effects are generally mild or moderate and may include back or joint pain, stomach pain or upset, or constipation. Follow dosing instructions carefully.

Please see important information on the following page.

Actonel.com
1-877-Actonel

Help fight fracture. Actonel.
Product Claim

DTC Ad

Brief Summary
Broadcast Advertising

“Major Statement”
– Information relating to the major side effects and contraindications

“Adequate Provision”
– Provides for dissemination of the PI

Recognizes the inability of broadcast advertisements of reasonable length to present and communicate this information effectively
Adequate Provision

- Toll-free number
- Simultaneously running magazine ad
- Reference to a healthcare provider
- Website
Flonase Detective Video Clip
Examples of Enforcement Actions

http://www.fda.gov/cder/warn/index.htm
Now available!
A complete line of Bupropion ER (SR).
AB Rated to Wellbutrin SR®

▲ 100 mg, 150 mg and 200 mg tablets
▲ 60, 100 and 500 count bottles

Look for the new Zyban® equivalent — Coming Soon!

SANDOZ

Eon Labs
“Reminder Ad” for Bupropion ER

- NOV issued for this “impermissible reminder ad”
- "Reminder advertisements... are not permitted for a prescription drug product whose labeling contains a boxed warning relating to a serious hazard associated with the use of the drug product."
- Labeling contains a boxed warning
- Ad fails to present brief summary
Viagra Shopping
Video Clip
Viagra “Reminder” TV Ad

- Makes representations about Viagra
- Approved indication not presented
- No risk information, no adequate provision
- Overstates efficacy of product
Trileptal Magnet

For every patient with a generalized seizure...

...there are 4 with partial seizures.

TRILEPTAL 
(oxcarbazepine)
150-300-600 mg tablets 300 mg/5 mL oral suspension
Trileptal – Lenticular Magnet

- Omission of indication and risk information
  - Effectiveness claims presented, but indication and risk are not
    - (Included on back of magnet--as a practical matter, this information is not communicated)
    - Magnet is designed to adhere to magnet surfaces—once displayed, content on back is not visible

- Encourages use in circumstances other than those for which shown to be safe and effective
  - Implies drug is indicated for generalized seizures
    - Full indication is not presented on front of magnet
    - Especially problematic in the view where only generalized seizures claim is visible
Enbrel Video Clip
Enbrel Corrective Video Clip
YAZ “Balloons” TV Ad
YAZ “Not Gonna Take It”
TV Ad
YAZ Corrective
Enforcement Trends

- Previous yearly average for the number of Warning Letters was generally 4-5
- 2008: 10 Warning Letters
- 2007: 9 Warning Letters

Possible reasons

- Prioritization of resources to have greatest impact on public health
- “Pushing the envelope”
- Aggressive promotion can be compliant with the regulations
Common Violations Occurring in 2005 - 2008

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

- **Web address:** [http://www.fda.gov/cder/ddmac](http://www.fda.gov/cder/ddmac)

- **Phone number:** (301) 796-1200

- **Fax number:** (301) 847-8444
Questions?