U.S. FOOD & DRUG ADMINISTRATION

# FDA Drug Topics:
# **FDA's Bad Ad Program**

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Office of Prescription Drug Promotion (OPDP)

Disclaimer: This presentation reflects the views of the author and should not be construed to represent FDA's views or policies.

# Objectives

- Discuss FDA's role in regulating prescription drug promotion
- Describe the role that healthcare professionals (HCPs) can play in protecting the public health by recognizing potentially false or misleading prescription drug promotion
- Explain how HCPs can effectively report potentially false or misleading prescription drug promotion to the FDA through the Bad Ad Program

# FDA's Mission

- The FDA is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.

- FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

# FDA's Mission

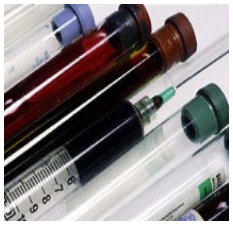
- The FDA is also responsible for advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health.

# FDA Organization

Office of the Commissioner

**C**enter for **F**ood **S**afety & **A**pplied **N**utrition

**C**enter for **D**rug **E**valuation & **R**esearch



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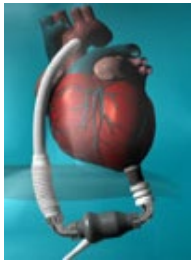

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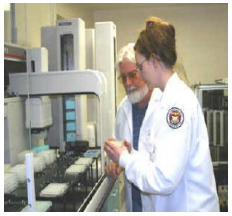


**O**ncology **C**enter of **E**xcellence

**C**enter for **T**obacco **P**roducts


**O**ffice of **R**egulatory **A**ffairs

Current as of 9/24/24

# Mission of the Office of Prescription Drug Promotion (OPDP)

- Protect the public health by helping to ensure that prescription drug promotion is truthful, balanced, and accurately communicated

- This is accomplished through comprehensive surveillance, compliance, research, and education programs, and by fostering better communication of labeling and promotional information to both healthcare professionals and consumers

# Regulatory Authority

Federal Food, Drug and Cosmetic Act and implementing regulations.

Prescription drug promotion **must**...

- Not be false or misleading
- Have a balance between efficacy and risk information
- Reveal material facts about the product being promoted, including facts about consequences that may result from the use of the drug

# 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 prescribing information (PI)

# What does OPDP regulate?

- Prescription drug promotional communications made by or on behalf of the drug's manufacturer, packer, or distributor, including:
  - TV and radio commercials
  - Sales aids, journal ads, and patient brochures
  - Drug websites, e-details, webinars, and email alerts

# Promotional Communications

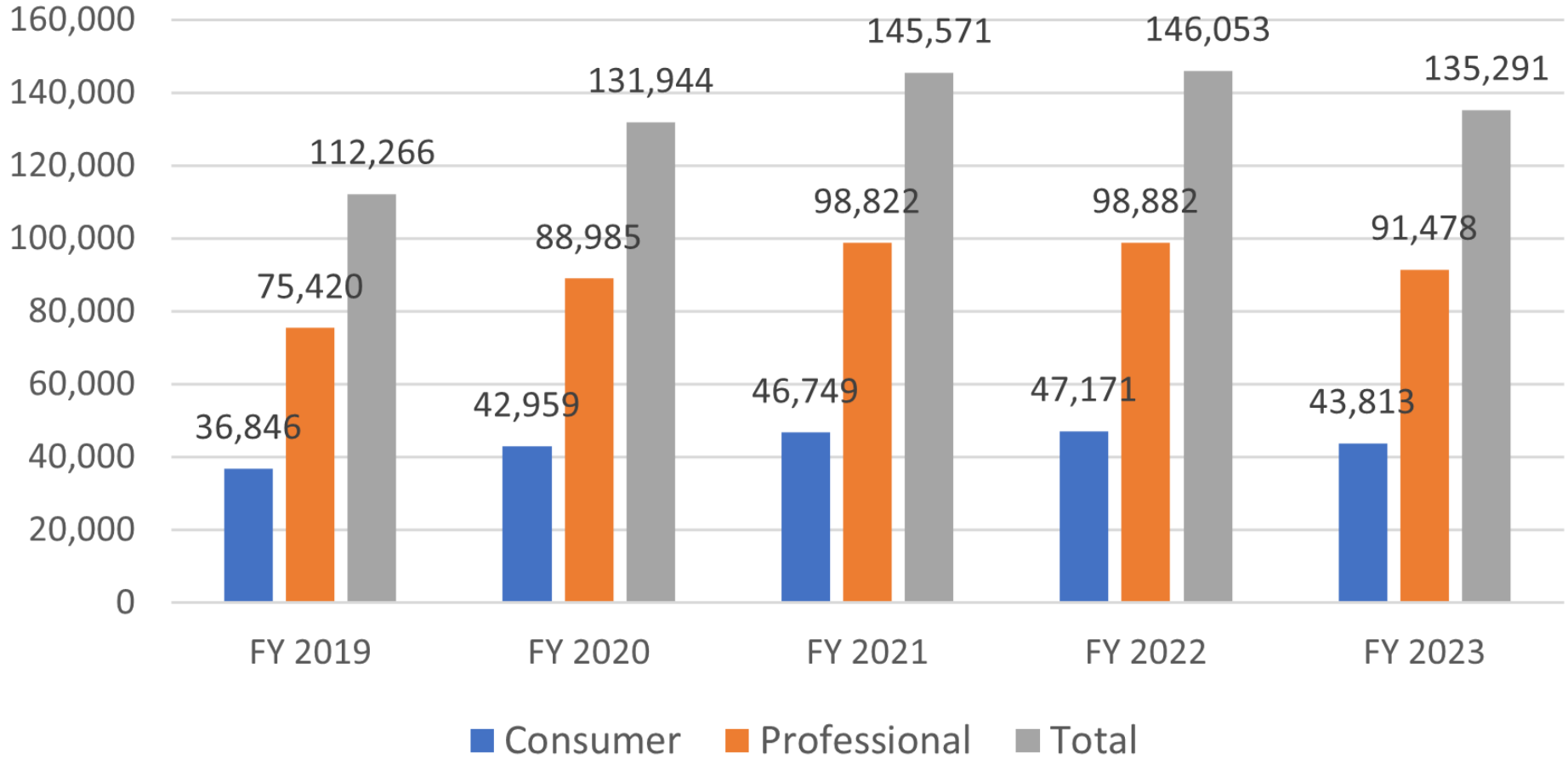
## Labeling

- Brochures, booklets, mailing pieces, exhibits, slide decks
- Accompanied by the FDA-approved product labeling

## Advertising

- Print advertisements in published journals, magazines, newspapers, and other periodicals
- Includes a “Brief Summary” of the drug’s side effects, contraindications, and effectiveness
- Broadcast (e.g., TV, radio, telephone communication systems)

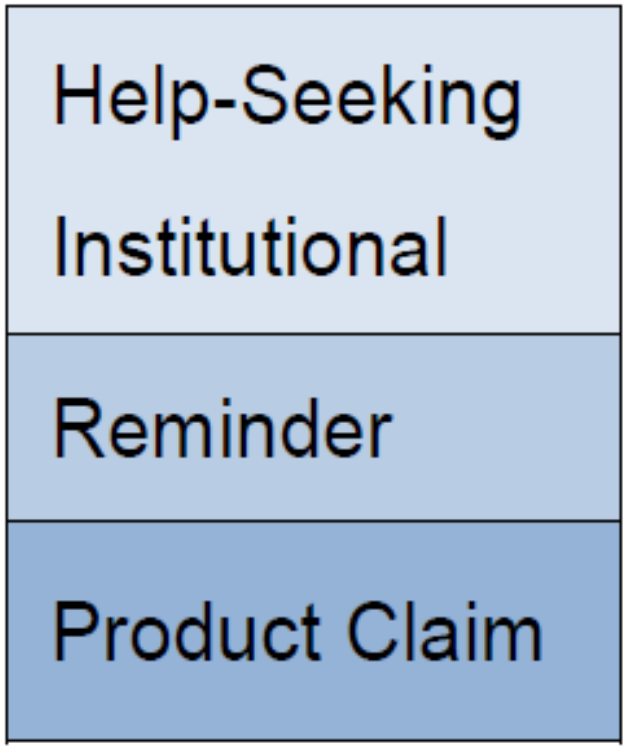
# Submissions to OPDP



# Misconceptions

- FDA “legalized” DTC advertising in the late 1990’s
- Industry spends most of its advertising budget on DTC advertising
- FDA has the authority to ban DTC advertising
- FDA approves ads
- FDA regulates “good taste”

# Types of Promotional Communications




**Do not** make any representations about a specific product

# Product Claim Communications

- Include representations or suggestions relating to the promoted drug product
- Must not be false or misleading
- Must reveal material facts about the product being promoted, including facts about consequences that may result from the use of the drug
- Must include a balanced risk and efficacy presentation ("fair balance")
- Must be accompanied by the Brief Summary or PI (advertising vs promotional labeling)

# Fictitious Examples

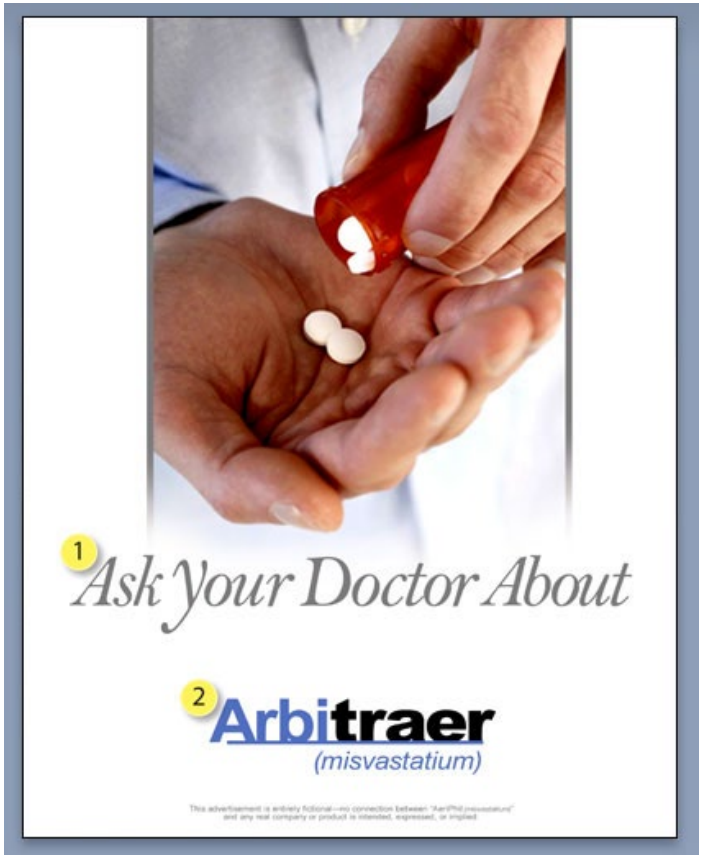
- **Drug**: Arbitraer (misvastatium) 100 mg tablets
- **Firm**: ACE Pharmaceuticals
- **Indication**: To treat seasonal allergy symptoms in adults

# Product Claim

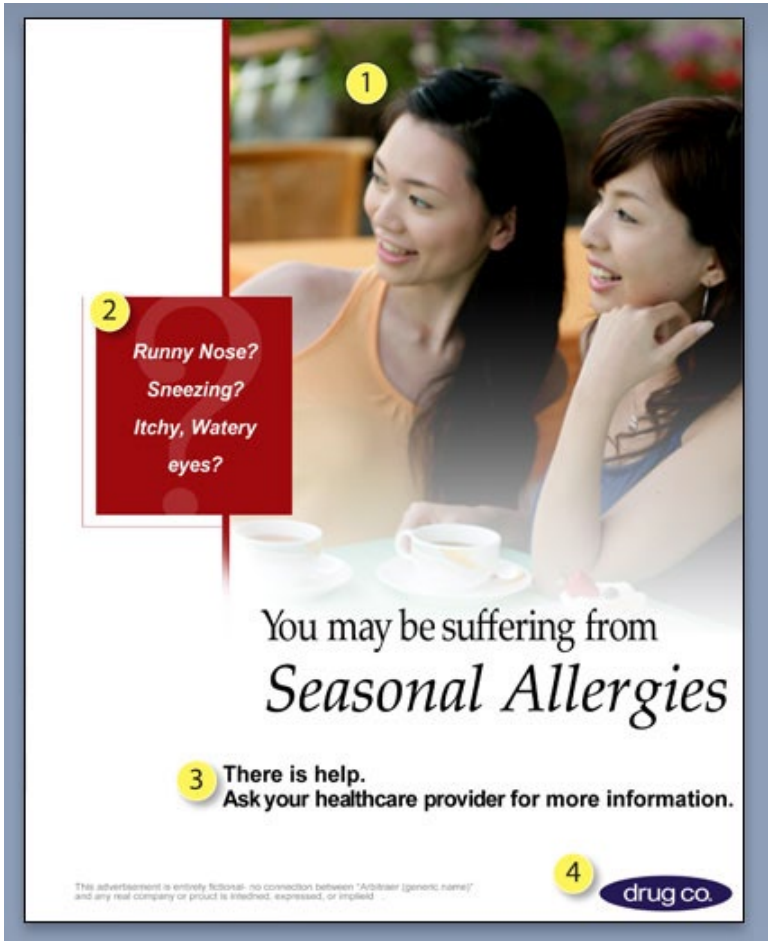
# Reminder Promotion

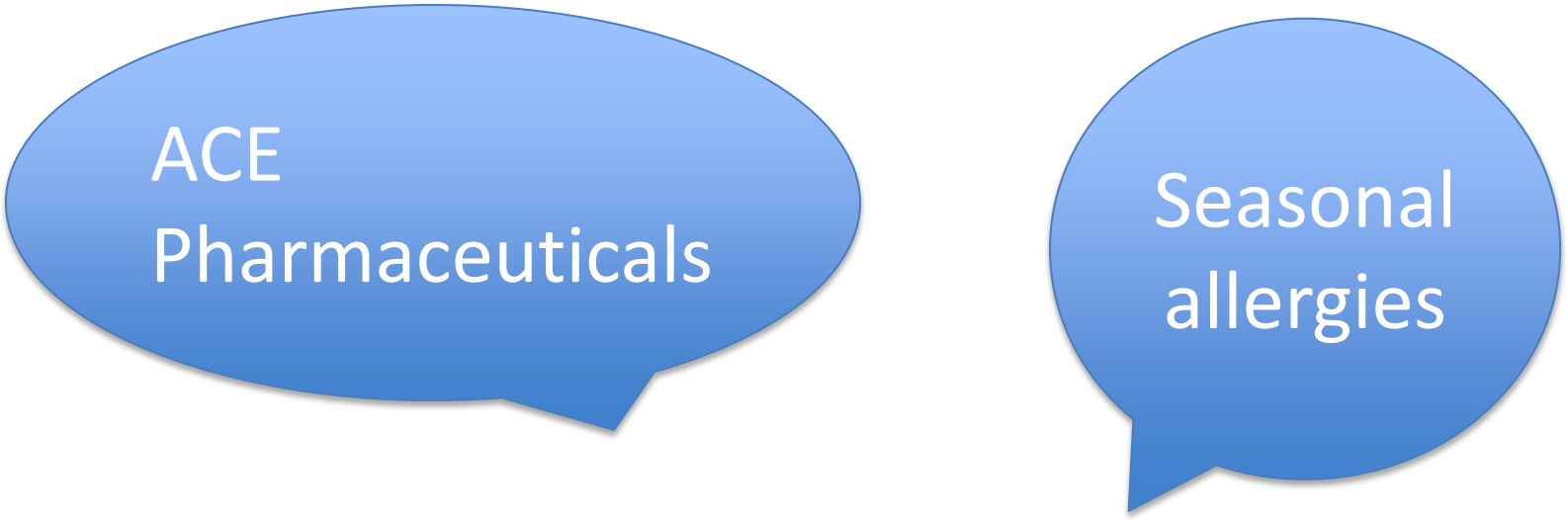
- Must include proprietary *and* established name
- May call attention to drug name but may NOT contain any representation or suggestion relating to the advertised drug product
- May include quantitative ingredient information, dosage form, package contents, price, name of manufacturer, packer, distributor
- Not permitted for a drug with a Boxed Warning

# Reminder



# Help-Seeking or Disease Awareness






**Institutional**

# 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

# What does OPDP do?

- Advice to industry
- Advice within FDA
- Guidance and policy development
- Research
- Surveillance and compliance

# Advice to Industry

- Provide comments on proposed promotional communications
  - ***Voluntary*** request for review
  - Launch materials for new drugs or new indications
  - Direct-to-consumer (DTC) broadcast ads
  - Non-launch materials

# Surveillance

- OPDP's routine surveillance activities include:
  - Monitoring drug promotional materials sent to us by industry as required
  - Monitoring medical convention exhibit halls
  - Monitoring drug promotion on the internet and social media
  - Reviewing complaints

# Common Violations

- Make claims that are not appropriately supported
- Misrepresent data from studies
- Overstate the drug's benefits

# Common Violations (cont.)

- Omit or downplay risk information
- Omit material facts about the drug
- Fail to present a “fair balance” of risk and benefit information

# Limitations to Surveillance

- Our routine surveillance activities do not allow us to monitor certain types of drug promotion, such as what occurs in places such as HCP offices, industry-sponsored dinner programs, and promotional speaker sessions

- That's one of the reasons why we developed the **Bad Ad Program**


FDA

- FDA-sponsored outreach program to educate HCPs about the role they can play in helping FDA ensure that prescription drug promotion is truthful and not misleading
- Bad Ad's dual mission:
  - Education and Outreach
  - Reporting Potential Violations
- Over 3,000 reports received since 2010 of potentially false or misleading prescription drug promotion


FDA

- Bad Ad Education and Outreach
  - Pharmaceutical companies spend billions of dollars each year to promote drugs, yet many HCPs are not trained to identify false or misleading promotion
  - Main educational outreach includes:
    - Free online course
    - Case studies for educational settings
    - Media campaigns and conference outreach

# Reporting Potential Drug Promotion Issues

- Any HCP can report potentially misleading promotion to OPDP by:
  - Sending an e-mail to **BadAd@fda.gov** or
  - Calling **855-RX-BADAD** (855-792-2323)

- Reports can be submitted anonymously. However, FDA encourages you to include contact information in case follow-up is necessary.

# What will OPDP do with your complaint?

- Once a Bad Ad complaint is received, OPDP will evaluate it to determine if compliance action is warranted

- If OPDP finds the promotion to be false or misleading, we may move forward with a risk-based compliance strategy to put a stop to the promotion ourselves or refer it for further criminal investigation

- If a complaint does not warrant compliance action at the time, it can still serve as valuable information in focusing our ongoing surveillance activities


FDA

# Warning Letter Example:

# Zolpimist (zolpidem tartrate) oral spray (C-IV)

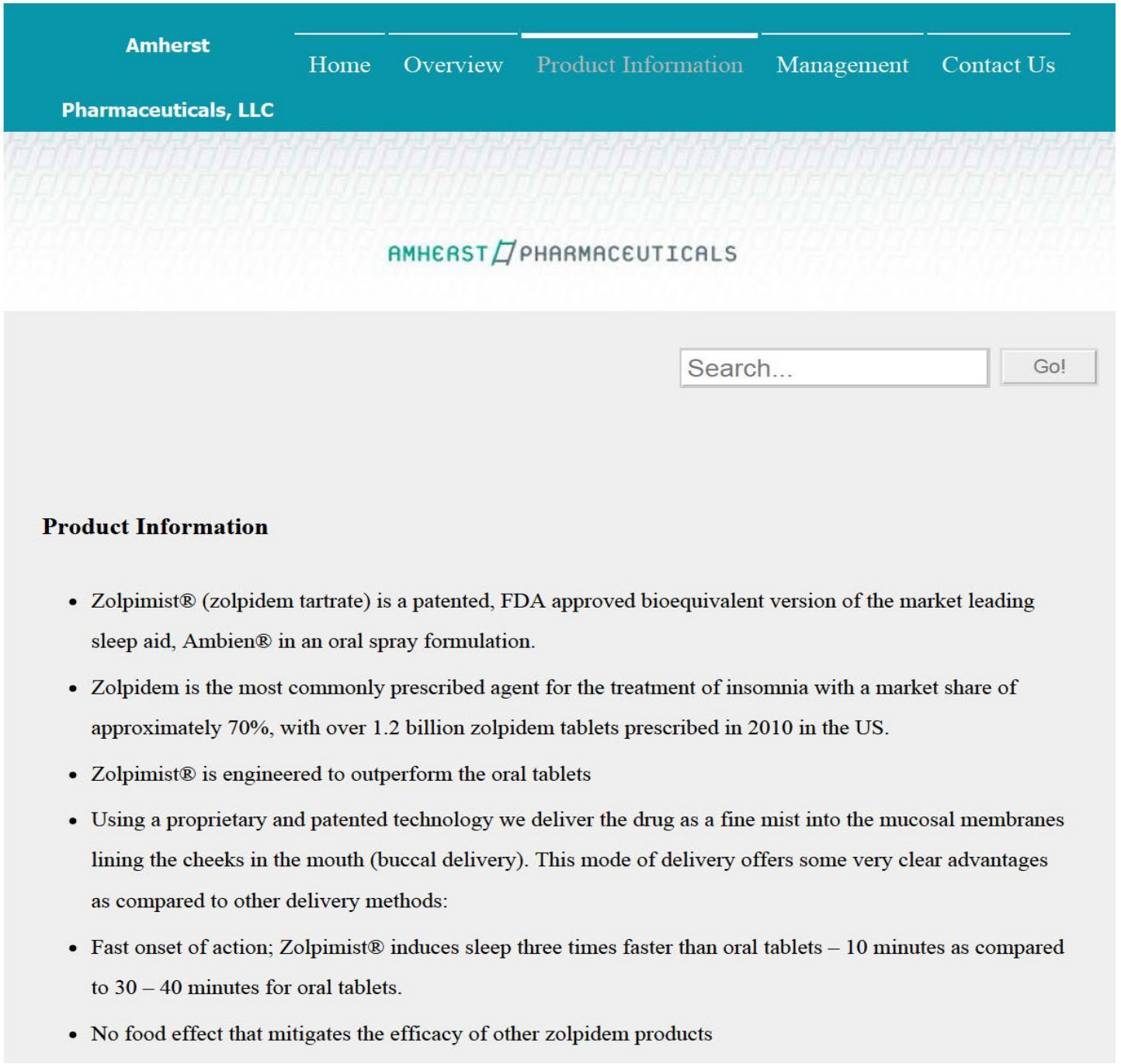
# Example: Zolpimist

Indication: Indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation. Zolpidem tartrate has been shown to decrease sleep latency for up to 35 days in controlled clinical studies…. The clinical trials performed in support of efficacy were 4-5 weeks in duration with the final formal assessments of sleep latency performed at the end of treatment.

# Example: Zolpimist

- Warning and Precautions: CNS depressant effects and next day impairment, need to evaluate for co-morbid diagnoses, severe anaphylactic and anaphylactoid reactions, abnormal thinking and behavioral changes, use in patients with depression, respiratory depression, and withdrawal effects

- The most common adverse reactions reported with Zolpimist were drowsiness, dizziness, diarrhea, and “drugged feelings”


Amherst
Pharmaceuticals, LLC
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Product Information
• Zolpimist® (zolpidem tartrate) is a patented, FDA approved bioequivalent version of the market leading sleep aid, Ambien® in an oral spray formulation.
• Zolpidem is the most commonly prescribed agent for the treatment of insomnia with a market share of approximately 70%, with over 1.2 billion zolpidem tablets prescribed in 2010 in the US.
• Zolpimist® is engineered to outperform the oral tablets
• Using a proprietary and patented technology we deliver the drug as a fine mist into the mucosal membranes lining the cheeks in the mouth (buccal delivery). This mode of delivery offers some very clear advantages as compared to other delivery methods:
• Fast onset of action; Zolpimist® induces sleep three times faster than oral tablets – 10 minutes as compared to 30 – 40 minutes for oral tablets.
• No food effect that mitigates the efficacy of other zolpidem products


FDA

# Warning Letter Example:

# Diclegis (doxylamine succinate and pyridoxine hydrochloride)

# Example: Diclegis

- Indication: Treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management.

- Limitations of Use: Has not been studied in women with hyperemesis gravidarum.

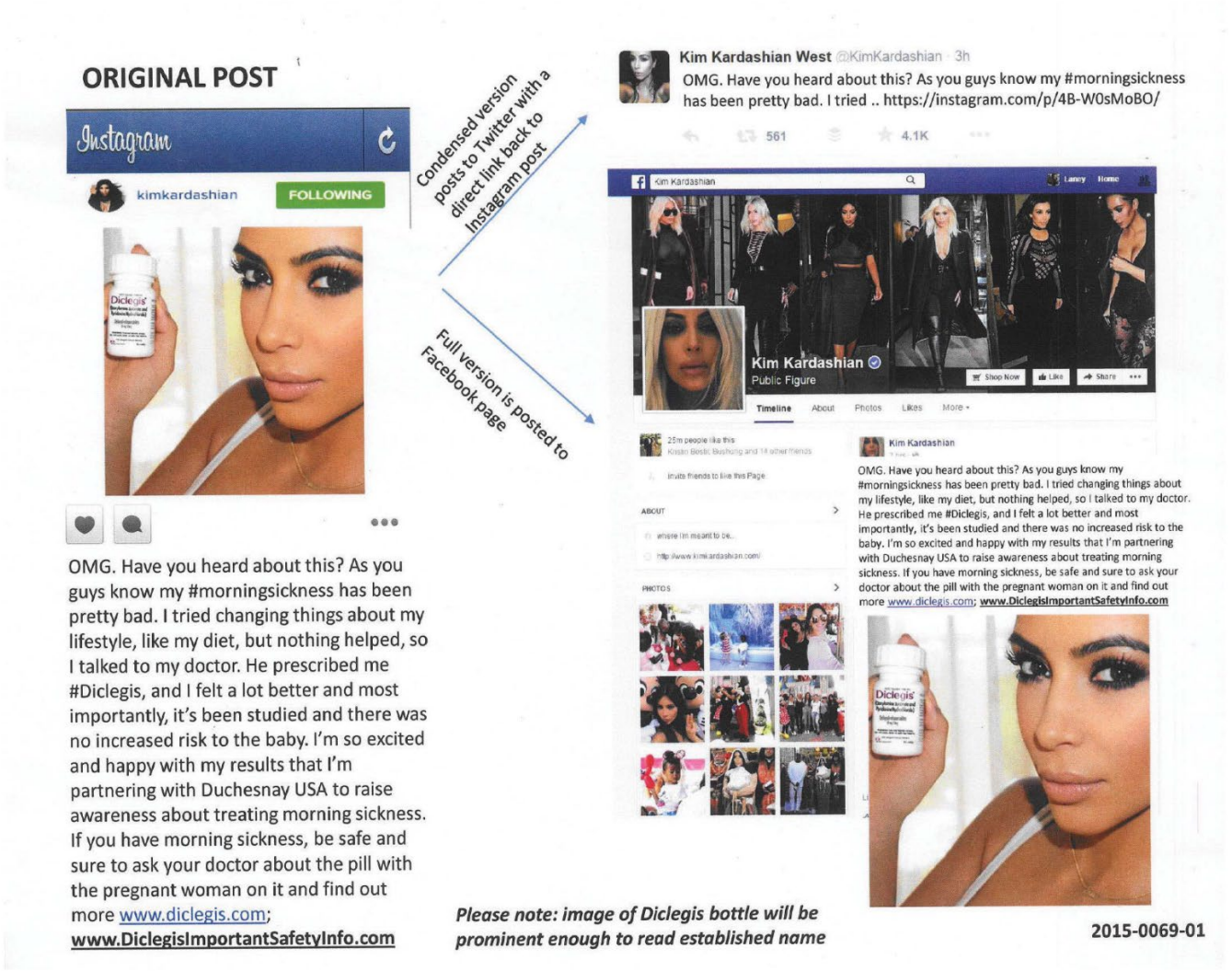
- Contraindications: Diclegis is contraindicated in women with known hypersensitivity to doxylamine succinate, other ethanolamine derivative antihistamines, pyridoxine hydrochloride or any inactive ingredient in the formulation, as well as in women who are taking monoamine oxidase inhibitors (MAOIs).

# Example:Diclegis

- Warning and Precautions regarding activities requiring mental alertness and concomitant medical conditions.

- The most common adverse reaction reported with Diclegis was somnolence.

# Diclegis – Social Media Post




FDA

- Phone: **855-RX-BADAD**
  (855-792-2323)
- E-Mail: **BadAd@fda.gov**
- More Info: **www.fda.gov/BadAd**

# References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- The Bad Ad Program. (2024, May 31). U.S. Food and Drug Administration. https://www.fda.gov/drugs/office-prescription-drug-promotion/bad-ad-program
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# QUESTIONS?


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