OPDP Update on Oversight of Prescription Drug Promotion

Thomas Abrams
Director
Office of Prescription Drug Promotion
Food and Drug Administration
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Topics

- Policy and Guidance Development
- Enforcement Overview

Goal and Objectives

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

Mechanisms for Meeting Objectives

- Voluntary compliance program
  - Guidance documents
  - Requests for comments on draft promotional materials
  - Educational efforts
- Comprehensive surveillance and enforcement program
- Social Science research program

Guidance Development

Guidance Development

- Follows Good Guidance Practices (GGPs)
  - Comments submitted to docket of draft guidances
  - Comments are reviewed and considered and may lead to revisions to draft guidances as they are being finalized and published as final or draft
  - OPDP website for draft and final guidances:
    - http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm109905.htm#Guidances

- Seven draft guidances published since January 2014
  - 2 on the distribution of scientific and medical publications
  - 3 on social media
  - 1 on consumer brief summaries
  - 1 on electronic submissions of promotional materials

Distributing Scientific and Medical Publications on Unapproved New Uses – Recommended Practices

- Recommendations for firms on their distribution of scientific and medical publications that discuss unapproved new uses (off-label uses)

- Previous guidance (2009) addressed recommendations for distribution of:
  - Scientific and medical journal articles
  - Reference texts

- Revisions made in response to comments/questions
  - Provides additional clarity about the distinction between practices for distribution of scientific/medical journal articles and reference texts
  - Adds new section on distribution of clinical practice guidelines

Distributing Scientific and Medical Publications on Risk Information for Approved Drugs and Licensed Biological Products-Recommended Practices

- Focuses on distribution of scientific and medical journal articles that discuss new risk information for approved uses of approved drugs and biological products
- Addresses questions from our stakeholders
- Safety profile of a drug evolves throughout its lifecycle as the extent of exposure to the product increases
- Important that healthcare professionals receive new risk information
- Nothing in draft guidance is intended to change a firm's existing obligation under the FD&C Act, PHS Act, and implementing regulations to update the approved labeling of its products, to accurately reflect what is known about the safety profile of the drug, to ensure that the labeling is not false or misleading

Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics

- Factors taken into consideration to determine if product communications using interactive technologies are subject to FDA's postmarketing submission requirements

- FDA's recommendations for submitting interactive promotional materials
  - Addresses challenges of submitting real time communications

Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices

Describes FDA's current thinking about how firms that voluntarily choose to correct misinformation related to their products should respond when that misinformation is created or disseminated by independent third parties on Internet/social media platforms

Within scope of guidance

- Communications that a firm is *not* responsible for
  - Independent user-generated content (UGC) on a third-party site
  - Independent UGC on a firm's own forum

Outside scope of guidance

- Communications that a firm *is* responsible for
  - A firm's own advertising or promotional labeling

Internet/Social Media Platforms with Character Space Limitations – Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices

Describes FDA's current thinking about how firms that choose to present benefit information should present both benefit and risk information within promotion on Internet/social media platforms with ***character*** space limitations

Within scope of guidance

- Online microblog messaging (e.g., Twitter)
- Online paid search (e.g., Google/Yahoo "sponsored links")
- Future ***character-space-limited*** Internet/social media platforms (long-term applicability)

Outside scope of guidance

- Product websites
- Webpages on social media networking platforms (e.g., individual product webpages on Facebook, YouTube)
- Online web banners

Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Human Prescription Drugs

- Drafts published February 2015 and August 2015
- Responds to stakeholder requests for clarification for consumer brief summary
  - Clarifies risk information that should be included
  - Recommends formatting options
- Recommends the "consumer brief summary" be used in place of:
  - The traditional brief summary (risk portions of the PI) for consumer-directed print advertisements
  - The full PI for consumer-directed print promotional labeling

Recommendations regarding the "Consumer Brief Summary"

- Format #1 – Prescription Drugs Facts Box
  - Similar to OTC Drug Facts Box
    - Standardized headings, e.g. Uses, Warning,
- Format #2 – Question and Answer
  - Present information in Q&A format

Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs

- Describes the various types of submissions of promotional materials and general considerations for submissions submitted in paper or electronic (eCTD) format

What will be Required and When?

- What types of submissions will be required?
  - Promotional materials submitted in fulfillment of the postmarketing reporting requirements (i.e. Form FDA 2253 submissions)
  - Presubmissions of promotional materials for accelerated approval products

- When are they required?
  - 24 months after the issuance of ***this*** guidance in ***final*** form, firms will be required to submit all promotional submissions that fall within section 745A(a) electronically (e.g., in eCTD format)
  - Firms may—and are encouraged to—submit electronically other types of promotional material submissions

Electronic Submissions to OPDP

History

- Draft Guidance for Industry published April 2015
- OPDP began accepting electronic (eCTD) submissions in June 2015

Benefits of eCTD

- Improves efficiency of review work
- Reduces the physical space requirements for storage of promotional material and related materials and provides easier access to these materials
- Provides opportunities for firms to develop streamline processes to submit high volume 2253s electronically

Electronic Submissions to OPDP

Fiscal Year 2015

- 12 sponsors submitted a total of 72 promotional submissions which included 163 pieces
  - Started in June 2015

Fiscal Year 2016

- 60 sponsors have submitted a total of 2,433 promotional submissions which includes over 6,500 promotional pieces

Questions about Submissions

- To begin the process of submitting a sample (as well as other technical questions), email the Electronic Submission Support Team
  - ESUB@fda.hhs.gov
- Email address for questions regarding the draft guidance or eCTD submissions to OPDP
  - OPDPeCTD@fda.hhs.gov
- Email address for general submission questions for OPDP
  - CDER-OPDP-RPM@fda.hhs.gov
- OPDP Phone number
  - 301-796-1200

Public Hearing

- Federal Register Notice published September 1, 2016
  - 2-day public hearing to obtain input related to communications about unapproved uses of approved or cleared medical products by manufacturers, packers, and distributors, including their representatives
  - Hearing to be held on November 9-10, 2016
  - Link to FR Notice:
    - https://www.gpo.gov/fdsys/pkg/FR-2016-09-01/pdf/2016-21062.pdf
  - Link to FDA's webpage for the meeting:
    - http://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm489499.htm

Public Hearing

- FDA is responsible for protecting the public health by helping to ensure medical products meet the rigorous standards for safety and effectiveness for their intended uses that people have come to trust and expect

- FDA is carefully considering how company communications about unapproved uses may impact the health and safety of the American people

Public Hearing

- FDA is holding a public hearing to provide an opportunity for all parties to offer their perspectives and additional data to inform the agency's thinking as we examine our rules and policies and work toward issuing further guidance and/or regulations on this important health matter

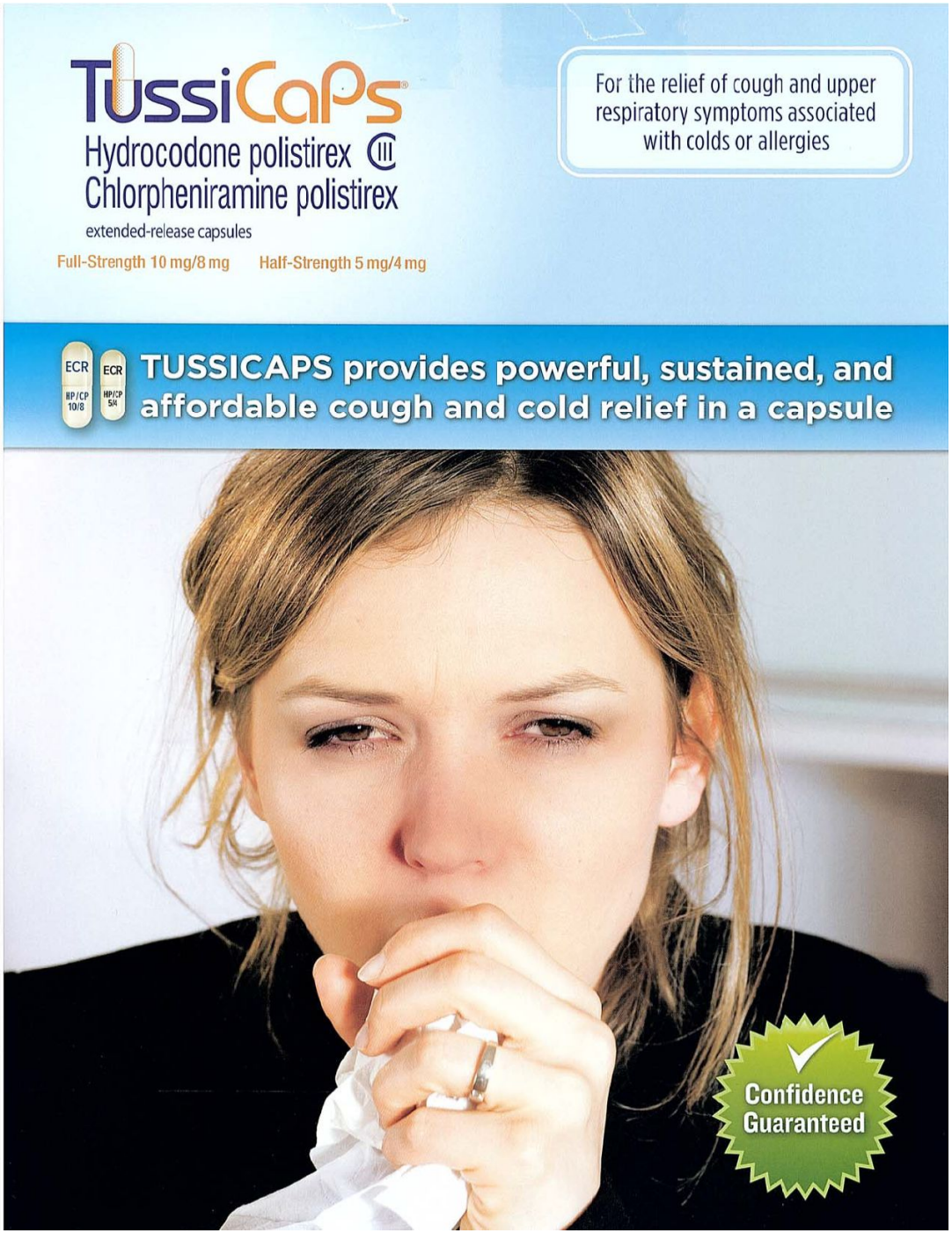
Enforcement

Common Violations
Cited in Regulatory Letters

- Omission and minimization of risk information
- Omission of material facts
- Overstatement of efficacy claims

TussiCaps Warning Letter

- Professional sales aid
- Violations included
  - Omission of material facts
  - Omission of risk information
- Indication:
  - TussiCaps are indicated for relief of cough and upper respiratory symptoms associated with allergy or a cold **in adults and children 6 years of age and older**.
- Contraindicated in children less than 6 years of age
  - Due to the risk of fatal respiratory depression
- Also PI indicates that caution should be exercised when administering to pediatric patients 6 years of age and older


TussiCaps
Hydrocodone polistirex
Chlorpheniramine polistirex
extended-release capsules
Full-Strength 10 mg/8 mg
Half-Strength 5 mg/4 mg
For the relief of cough and upper respiratory symptoms associated with colds or allergies
ECR
HP/CP 10/8
ECR
HP/CP 5/4
TUSSICAPS provides powerful, sustained, and affordable cough and cold relief in a capsule
Confidence Guaranteed

Powerful Relief

- Efficacious, safe, and proven combination of ingredients provide cough and cold symptom relief

Each extended-release TUSSICAPS capsule contains the equivalent of

	Full-Strength	Half-Strength
Hydrocodone bitartrate	10 mg	5 mg
Chlorpheniramine maleate	8 mg	4 mg

in a polistirex formulation that provides for twice-daily dosing

Decongestant-free, sugar-free

Sustained Relief

- Extended relief from uncontrolled coughs eliminates the need for middle of the night dosing
- TUSSICAPS is dosed every 12 hours

12 HOUR DOSAGE

TussiCaps Warning Letter

- Omission of material facts
  - Page 1: For the relief of cough and upper respiratory symptoms associated with colds or allergies
    - Omission of “in adults and children 6 years of age and older”
  - Page 2: Image of coughing young child
- Contraindicated in children less than 6 years of age
  - Due to the risk of fatal respiratory depression
- Also PI indicates that caution should be exercised when administering to pediatric patients 6 years of age and older.

TussiCaps Warning Letter

- Omission of Risk Information
  - Efficacy claims made for TussiCaps but failed to present:
    - Any of the contraindications
    - Warnings and precautions about respiratory depression, head injury and increased intracranial pressure, acute abdominal conditions, obstructive bowel disease, and pediatric use
    - Association with drug abuse and dependence
    - Adverse reactions such as nausea and vomiting, sedation, drowsiness, mental clouding, impairment of mental and physical performance, anxiety, fear, dizziness, mood changes

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/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCcompanies/default.htm

OPDP Contact Information

- **Telephone Number**
  - 301-796-1200
- **Fax Numbers**
  - 301-847-8444
  - 301-847-8445
- **Submission Address**
  - Food and Drug Administration
    Center for Drug Evaluation and Research
    Office of Prescription Drug Promotion
    5901-B Ammendale Road
    Beltsville, MD 20705-1266