FDA Update on Oversight of Prescription Drug Promotion

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

- **Medical Product Communications That Are Consistent With the FDA-Required Labeling – Questions and Answers**
  Guidance for Industry
- **Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities – Questions and Answers**
  Guidance for Industry
- **Draft Guidance: Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer Promotional Labeling and Advertisements**

Medical Product Communications That Are Consistent With the FDA-Required Labeling – Questions and Answers Guidance for Industry

Purpose of Guidance

Provides FDA's thinking regarding when:

Communications that present information about a product that is not contained in the FDA-required labeling

Are considered to be consistent with the FDA-required labeling

What This Guidance Does

- **Describes how FDA determines whether a firm's communication is consistent with the FDA-required labeling (CFL)**

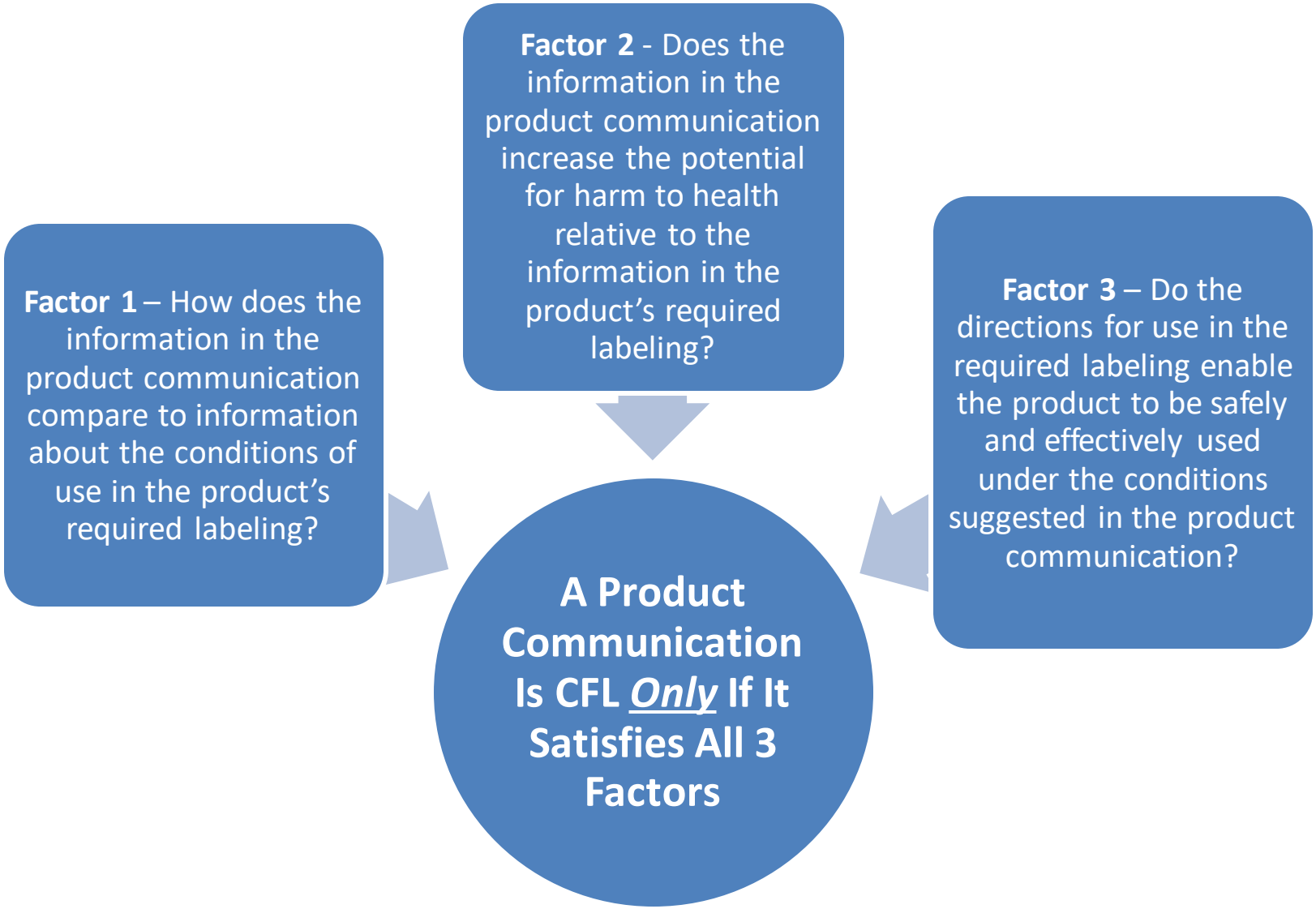
- **Clarifies for firms that FDA does not intend to rely on product communications that are determined to be CFL to establish a new intended use, different from the use(s) for which the product is legally marketed**

- **Provides general recommendations for conveying CFL information in a truthful and non-misleading way**

How Will FDA Assess Communications?

- **FDA uses a 3-factor approach to evaluate whether a communication is consistent with the product's FDA-required labeling (CFL)**
- **FDA also evaluates whether FDA-regulated communications are truthful and non-misleading**
  - **The guidance provides recommendations for firms to consider when developing CFL promotional communications**

The 3-Factor CFL Analysis



A Promotional Communication Is Determined to Be CFL… Now What?

Considerations for Truthful and Non-misleading CFL Promotional Communications

- **Recommendations for truthful and non-misleading CFL promotional communications are outlined in the guidance, including recommendations regarding evidentiary support**

- **CFL promotional communications that lack appropriate evidentiary support are likely to be false or misleading, and can cause patient harm**

- **FDA will not consider a CFL promotional communication to be false or misleading based only on the lack of evidence sufficient to satisfy the applicable approval/clearance standard**

Additional Consideration

- **FDA-regulated promotional materials must also comply with other applicable requirements of the Food, Drug & Cosmetic Act and implementing regulations**
  - **E.g., for prescription drugs, appropriate disclosures of risk information, fair balance**

Changes from the Draft Guidance

- **Clarifies the scope of communications covered by the guidance**
- **Explains factors 2 and 3 of the CFL analysis and includes examples to illustrate their application**
  - **Also explains that for devices that are 510(k)-cleared or -exempt, firms should refer to existing device regulations and guidance and need not separately analyze under the factors discussed in Q2/A2**
- **Expands on the categories and examples of information that could be CFL**
- **Clarifies recommendations for truthful and non-misleading CFL promotional communications**

Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities – Questions and Answers Guidance for Industry

Purpose of Guidance

To provide answers to common questions regarding firms' communications with payors, formulary committees, and similar entities regarding the following:

- Health care economic information (HCEI) regarding approved prescription drugs
- **HCEI regarding approved/cleared medical devices**
- Communications regarding unapproved products and **unapproved uses of approved/cleared medical products**

Communication of HCEI to Payors Regarding Approved Drugs

Brief Background

Sec. 502(a) of the FD&C Act: False or misleading labeling

1997

FDAMA sec. 114

Amended sec. 502(a) to include a provision regarding the communication of HCEI to payors about approved drugs

2016

21st Century Cures Act

Further amended HCEI provision in sec. 502(a)

What does this guidance do?

Health Care Economic Information:

- Provides FDA's recommendations for how firms can communicate HCEI about approved drugs to payors in accordance with section 502(a) of the FD&C Act.

HCEI Definition

- Includes monetary costs and resource utilization*
  - Related to clinical outcomes of treating, preventing or diagnosing a disease
- Can be presented in a variety of ways*
  - Evidence dossier
  - Reprint of a publication from a peer-reviewed journal
  - Slide presentation
  - Payor brochure
  - Software package comprising a model with a user manual

**These are examples; the list is not meant to be all inclusive.*

Scope of Audiences

Payors, formulary committees, or other similar entities

- Possess knowledge and expertise in the area of health care economic analysis[1]
- Perform selection or acquisition of drugs for coverage or reimbursement on a population basis on behalf of a health care organization
- Have range of expertise in multiple disciplines and established procedures for carefully considering evidence about medical products

[1] Section 502(a) of the Federal Food, Drug, and Cosmetic Act

Scope of Audiences (cont.)

- Includes public and private payors
- Recommendations do not apply to communications to other audiences, such as health care professionals or consumers
- Does include health care professionals that have multiple roles
  - HCP who serves on a formulary committee and provides care to individual patients would fall within the scope of the guidance when performing professional responsibilities for a payor regarding the selection of drugs for coverage or reimbursement

Communication to Payors Regarding Approved or Cleared Medical Devices

Communications by Firms to Payors Regarding Unapproved Products and Unapproved Uses of Approved/Cleared Products

What does this guidance do?

Unapproved Products:

- Provides FDA's current thinking on communications by firms to payors about unapproved products
- Includes drugs and medical devices not yet approved/cleared/licensed by FDA for any use

Unapproved Uses of Approved/Cleared/Licensed Products:

- Provides FDA's current thinking on communications by firms to payors regarding unapproved uses of their approved drugs and cleared/licensed medical devices

Key Concepts

- Types of information
- Recommendations
- Inappropriate communications
- Additional considerations

Types of Information

- Product information
  - Drug class, device description
- Information about the indication sought
  - Information from clinical study protocol(s) about endpoints and patient populations
- Anticipated timeline for possible FDA approval/clearance/licensure of the product or new use

Types of Information (cont.)

- Product pricing information
- Patient utilization projections
- Product related programs or services
- Factual presentations from results of studies
  - Clinical studies of drugs or devices
  - Bench tests that describe device performance
  - No characterizations/conclusions about safety or effectiveness

Draft Guidance: Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer Promotional Labeling and Advertisements

Purpose of Draft Guidance

The draft guidance, if finalized, would provide recommendations for presenting quantitative efficacy and risk information in DTC promotional labeling and advertisements for prescription human drugs and biological products and prescription animal drugs and DTC promotional labeling for OTC animal drugs

Topics Covered by Guidance

- Presenting probability information in terms of absolute frequencies, percentages, and relative frequencies
- Formatting quantitative efficacy or risk information
- Using visual aids to illustrate quantitative efficacy or risk information
- Providing quantitative efficacy or risk information for the treatment group and the control group

Probabilities Presentations

- Absolute Frequencies and Percentages
  - Firms should convey quantitative information in terms of absolute frequencies (e.g., 57 out of 100) or percentages (57%)
  - Can improve consumers' comprehension and ability to recall the information for probabilities

Probabilities Presentations

- Relative Frequencies
  - Research suggests that consumers do not understand relative frequencies as easily as other formats for presenting probabilities such as absolute frequencies or percentages
  - If used, should add context of the corresponding absolute probability measures

Formatting

- Present the information in the same numerical format throughout the promotional piece
- Use frequencies with the same denominator when providing more than one absolute frequency and consider using denominators that are multiples of 10
- Express probabilities using whole numbers to the extent that the probabilities in whole numbers accurately reflect the numerical value being described in the promotional piece

Visual Aids

- Consider the communication's purpose and objectives
  - Bar graph for comparisons between probabilities
  - Line graph for trends or changes over time
- Include title, header, or caption and identify the visual aid's variables, scales and axes (when applicable)
- Make displays of numeric information proportionate to the quantity being described
- Include visual representations of both the numerator and denominator of ratios or frequencies

Control Groups

- Provide information from both the treatment and the relevant control group

OPDP Web Resources

- OPDP Home Page
  - http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm090142.htm
- Guidances
  - http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm109905.htm#Guidances
- Social Science Research
  - https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm090276.htm
- Warning and Untitled Letters
  - www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/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


FDA
U.S. FOOD & DRUG
ADMINISTRATION