Advertising and Promotion of Medical Devices

Scott D. Danzis & Amy B. Leiser

November 2022

COVINGTON

BEIJING BRUSSELS DUBAI FRANKFURT JOHANNESBURG LONDON LOS ANGELES
NEW YORK PALO ALTO SAN FRANCISCO SEOUL SHANGHAI WASHINGTON

www.cov.com

Agenda

Background and Basics

Special Topics:

- Preapproval Communications
- Comparative Claims
- General v. Specific Claims

Promotion Using Social Media

Testimonials and Endorsements

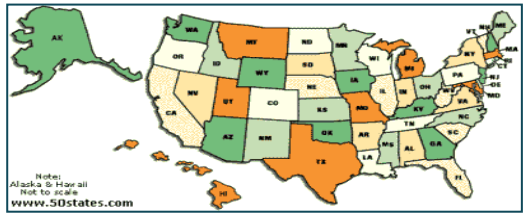
Off-Label Communications

Background and Basics

Promotion Enforcement Landscape

FEDERAL TRADE COMMISSION
FOR THE CONSUMER

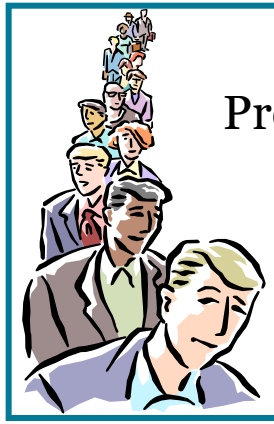
State AGs



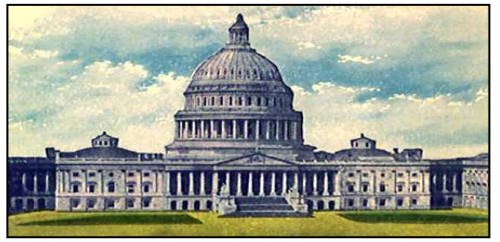
FDA

DOJ and OIG

Med Tech



Product Liability Lawsuits



Congressional Investigations

Competitors

Unfair Competition: Lanham Act Claims

Key Statutes Impacting Promotional Activities

- Federal Food, Drug, and Cosmetic Act
- Federal Trade Commission Act
- Lanham Act
- False Claims Act
- Anti-kickback Statute
- Sunshine Act and state disclosure statutes
- Foreign Corrupt Practices Act (FCPA)

Who Regulates?

- Labeling
- Advertising of restricted devices
- Other promotional communications (including others speaking on company behalf) can be evidence of “intended use”
- Advertising of non-restricted devices

Labels, Labeling, Advertising

Labels

FDCA 201(k)

Display of written, printed, or graphic matter upon the immediate container of any article.

Labeling

FDCA 201(m)

Written, printed, or graphic material which:

- "Accompanies" the device
- Supplements or explains the product
- Is disseminated by the manufacturer

Includes brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house newsletters, letters, PowerPoint presentations, etc.

Internet, Social Media

Advertising

21 C.F.R. 202.1(l)(1) (drug regs)

Advertising is media-based materials such as:

- Magazines
- Newspapers
- Professional journals
- Radio and TV commercials

Federal Food, Drug and Cosmetic Act (FDCA)

Misbranding

FDCA § 502

- Labeling is false or misleading
- Labels/labeling lack required information or prominence
- Failure of labeling to include “adequate directions for use” for all intended uses of device
- Failure to include information required for advertising of restricted devices
- If device lacks a 510(k) for an intended use, and a 510(k) is needed

Adulteration

FDCA § 501

- If device lacks a PMA for an intended use, and a PMA is needed.
- If device is approved under a PMA and lacks an investigational device exemption (IDE) for an investigational use.

Federal Trade Commission Act

- FTC regulates advertising of non-restricted medical devices
- Relevant provisions of FTC Act:
  - Section 5: Prohibits “unfair or deceptive acts or practices”
  - Section 12: Prohibits dissemination of any “false advertisement” likely to induce the purchase of devices, drugs, cosmetics, food, or services
  - Section 15: Defines “false advertisement” as ad that is misleading in a material respect

Overview of Promotion Requirements

Claims must be <u>Truthful</u> and <u>Not Misleading</u>

- Express & Implied Claims
- Omissions

Claims must be <u>Substantiated</u>

- Need "valid scientific evidence" supporting claims
- Evidence required may vary based on the claim and device characteristics, other factors

Claims must be "<u>On-Label</u>"

- Approved in a PMA
- Cleared in a 510(k)
- Consistent with Exemption from 510(k)

Claims = statements regarding the actual or comparative safety, effectiveness or performance of a device

Special Topics: Pre-Approval Communications

Display of 510(k)-Pending Devices

- FDA policy (CPG § 300.600) going back to 1978:

Although a firm may advertise or display a device that is the subject of a pending 510(k) -- in the hope that FDA will conclude that the device is substantially equivalent to a pre-amendments device -- a firm may not take orders, or be prepared to take orders, that might result in contracts of sale for the device unless limited to research or investigational use.

- Based on this language, a practice has emerged to display or advertise a device that is the subject of a submitted (or filed?) 510(k)

Check out our next-generation MRI!!

~~*Safe and Effective!*~~

~~*Place your Order Now!*~~

Pending 510(k) clearance, not available for sale within the United States

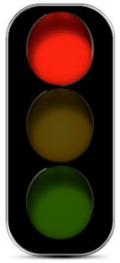
FDA Guidance (June 2018)

- "FDA does not intend to object to" communications about "health care economic information (HCEI)" with "payors, formulary committees, and similar entities" about products in development, which may include:
  - Product information and indication sought;
  - Endpoints and populations studied, and factual presentations of results from clinical or preclinical studies (i.e., no characterizations or conclusions should be made regarding the safety or effectiveness of the product");
  - Anticipated timeline for FDA action;
  - Product pricing information and planned outreach/marketing strategies;
  - Product-related programs/services (e.g., patient support programs).
- Must also:
  - Include a clear statement that product is under investigation;
  - Provide information on stage of product development;
  - Follow up when information becomes outdated.

To Whom May Such Information be Provided?

Entities and persons making purchasing decisions for a population

"[P]ublic and private sector payors, formulary committees… technology assessment committees, … third party administrators, and other multidisciplinary entities that, on behalf of health care organizations, review scientific and/or technology assessments to make drug or device selection or acquisition, formulary management, and/or coverage and reimbursement decisions on a population basis."



HCPs making prescribing decisions and/or consumers

"[T]his guidance does not apply to … other audiences, such as health care providers who are making individual patient prescribing decisions or consumers (e.g., dissemination directed toward prescribers or consumers via a public website)."

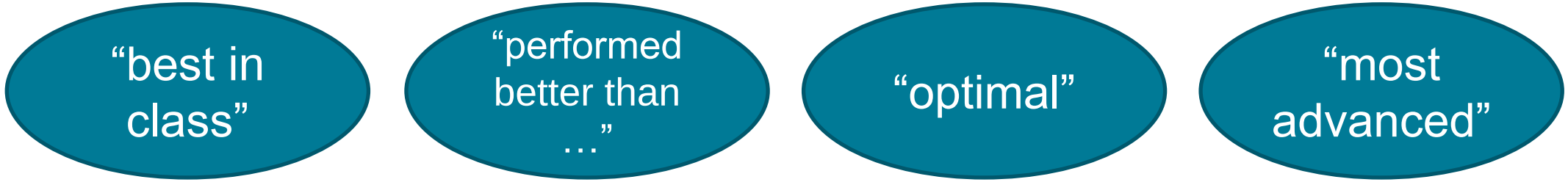
HCPs that have multiple roles

"This is not meant to suggest that individuals who have multiple roles, such as a health care professional who serves on a formulary committee and also provides care for individual patients, would not fall within the scope of the appropriate audience for this guidance when they are carrying out their professional responsibilities for selection of drugs for coverage or reimbursement for a payor, formulary committee, or similar entity."

Special Topics: Comparative and General v. Specific Claims

Comparative and Superiority Claims

- Comparative claims explicitly or implicitly compare two or more devices



  - A claim can be comparative even if no other device is expressly discussed
  - Presenting contrasting data is comparative claim even if no express comparative statements are made
- FDA regulations that a device can be misbranded through false or misleading comparisons to other products (see 21 C.F.R. § 801.6)

Comparative Claims

- Comparative claims (*e.g.*, safety, effectiveness) require head-to-head studies
  - FDA has repeatedly stated this principle in Warning Letters to drug and device companies.
- In some cases, comparison of published performance or technical specifications may be defensible:
  - *E.g.,* IFU to IFU comparisons of objective information (*e.g,* stent lengths or published tensile strengths for an implant).
  - Such comparison should not be made if the test methods used for the two products were known to be materially different.
  - Such comparisons cannot be used to imply or claim a comparative advantage in terms of clinical performance.
- Even if a comparison is appropriately substantiated, other standards apply, including requirement to be consistent with labeling.

Curatronic Warning Letter (Jan. 2013)

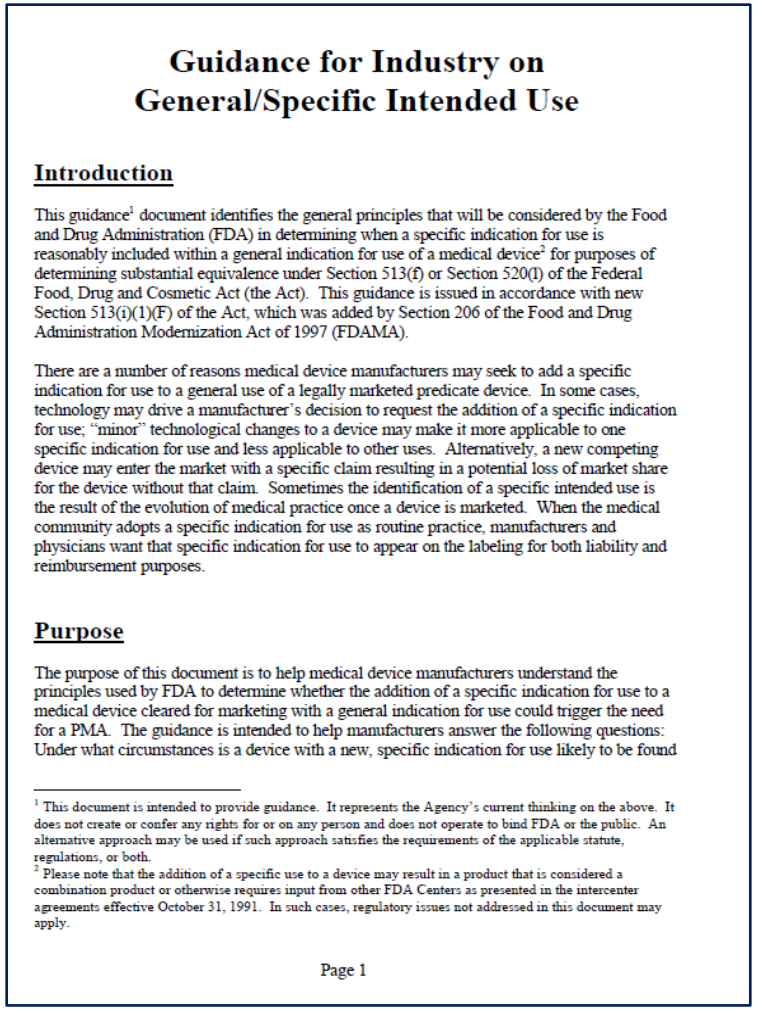
"The BioMove 5000 is not only the best Stroke Rehabilitation system in the world but also the easiest stroke therapy device for use by the stroke survivor."

"If the stroke survivor hardly has any movement left, the BioMove 5000 Pro device is the right choice as it is able to measure very weak EMG signals with its superior EMG detector and signal processing system."

FDA: Comparative claims regarding the device being the best and easiest stroke rehabilitation system in the world require clinical data and a new 510(k)

General v. Specific Use

- 510(k) clearance for a general use does not necessarily mean the device is cleared for a specific indication
- Key is interpreting intended scope of clearance and
  - Risks inherent in specific use
  - Knowledge base
  - Public health impact



Guidance for Industry on
General/Specific Intended Use

Introduction

This guidance[1] document identifies the general principles that will be considered by the Food and Drug Administration (FDA) in determining when a specific indication for use is reasonably included within a general indication for use of a medical device[2] for purposes of determining substantial equivalence under Section 513(f) or Section 520(l) of the Federal Food, Drug and Cosmetic Act (the Act). This guidance is issued in accordance with new Section 513(i)(1)(F) of the Act, which was added by Section 206 of the Food and Drug Administration Modernization Act of 1997 (FDAMA).

There are a number of reasons medical device manufacturers may seek to add a specific indication for use to a general use of a legally marketed predicate device. In some cases, technology may drive a manufacturer's decision to request the addition of a specific indication for use; "minor" technological changes to a device may make it more applicable to one specific indication for use and less applicable to other uses. Alternatively, a new competing device may enter the market with a specific claim resulting in a potential loss of market share for the device without that claim. Sometimes the identification of a specific intended use is the result of the evolution of medical practice once a device is marketed. When the medical community adopts a specific indication for use as routine practice, manufacturers and physicians want that specific indication for use to appear on the labeling for both liability and reimbursement purposes.

Purpose

The purpose of this document is to help medical device manufacturers understand the principles used by FDA to determine whether the addition of a specific indication for use to a medical device cleared for marketing with a general indication for use could trigger the need for a PMA. The guidance is intended to help manufacturers answer the following questions: Under what circumstances is a device with a new, specific indication for use likely to be found

[1] This document is intended to provide guidance. It represents the Agency's current thinking on the above. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.
[2] Please note that the addition of a specific use to a device may result in a product that is considered a combination product or otherwise requires input from other FDA Centers as presented in the intercenter agreements effective October 31, 1991. In such cases, regulatory issues not addressed in this document may apply.

Page 1

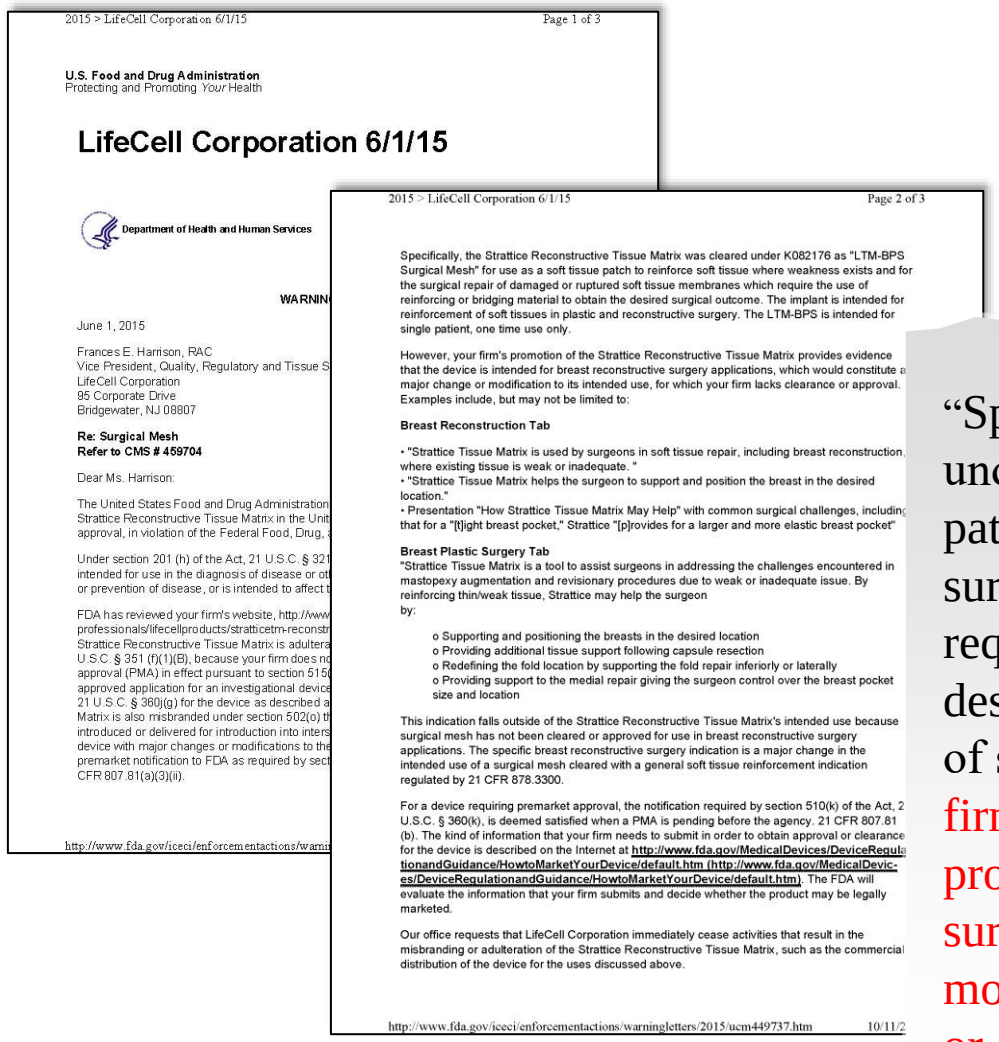
FDA Guidance Examples – Diagnostic Ultrasound

Ultrasound Device 510(k)-Cleared with general indication: evaluation of soft tissue

Specific claim	Specific claim
Aid in differentiation of benign from malignant breast lesions	Discrimination of small soft tissue parts (e.g. tendons, nerves)

▪ Specific indication is not substantially equivalent to general indication.
  ◦ Risk: Risk of false negatives leading to postponement of beast biopsy is far greater than risk of false negatives in general ultrasound studies
  ◦ Public health: Breast cancer is a leading cause of morbidity/mortality in US, any change in the management paradigm for suspicious lesions may have a profound impact on public health.
	▪ Specific indication is substantially equivalent to general indication
	  ◦ Risk: Specific indication is simply a statement of the types of anatomical detail that can be evaluated with ultrasound technology.

Warning Letter: Inappropriate Specific Claims



2015 > LifeCell Corporation 6/1/15 Page 1 of 3

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

LifeCell Corporation 6/1/15

Department of Health and Human Services

WARNIN

June 1, 2015

Frances E. Harrison, RAC
Vice President, Quality, Regulatory and Tissue S
LifeCell Corporation
95 Corporate Drive
Bridgewater, NJ 08807

Re: Surgical Mesh
Refer to CMS # 459704

Dear Ms. Harrison:

The United States Food and Drug Administration
Strattice Reconstructive Tissue Matrix in the Unit
approval, in violation of the Federal Food, Drug,

Under section 201 (h) of the Act, 21 U.S.C. § 321
intended for use in the diagnosis of disease or ot
or prevention of disease, or is intended to affect t

FDA has reviewed your firm's website, http://www
professionals/lifecellproducts/stratticetm-reconstr
Strattice Reconstructive Tissue Matrix is adultera
U.S.C. § 351 (f)(1)(B), because your firm does no
approval (PMA) in effect pursuant to section 515(
approved application for an investigational devic
21 U.S.C. § 360j(g) for the device as described a
Matrix is also misbranded under section 502(o) th
introduced or delivered for introduction into inters
device with major changes or modifications to the
premarket notification to FDA as required by sect
CFR 807.81(a)(3)(ii).

http://www.fda.gov/iceci/enforcementactions/warni

2015 > LifeCell Corporation 6/1/15 Page 2 of 3

Specifically, the Strattice Reconstructive Tissue Matrix was cleared under K082176 as "LTM-BPS Surgical Mesh" for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes which require the use of reinforcing or bridging material to obtain the desired surgical outcome. The implant is intended for reinforcement of soft tissues in plastic and reconstructive surgery. The LTM-BPS is intended for single patient, one time use only.

However, your firm's promotion of the Strattice Reconstructive Tissue Matrix provides evidence that the device is intended for breast reconstructive surgery applications, which would constitute a major change or modification to its intended use, for which your firm lacks clearance or approval. Examples include, but may not be limited to:

Breast Reconstruction Tab

- "Strattice Tissue Matrix is used by surgeons in soft tissue repair, including breast reconstruction, where existing tissue is weak or inadequate. "
- "Strattice Tissue Matrix helps the surgeon to support and position the breast in the desired location."
- Presentation "How Strattice Tissue Matrix May Help" with common surgical challenges, including that for a "[t]ight breast pocket," Strattice "[p]rovides for a larger and more elastic breast pocket"

Breast Plastic Surgery Tab

"Strattice Tissue Matrix is a tool to assist surgeons in addressing the challenges encountered in mastopexy augmentation and revisionary procedures due to weak or inadequate issue. By reinforcing thin/weak tissue, Strattice may help the surgeon
by:

- o Supporting and positioning the breasts in the desired location
- o Providing additional tissue support following capsule resection
- o Redefining the fold location by supporting the fold repair inferiorly or laterally
- o Providing support to the medial repair giving the surgeon control over the breast pocket size and location

This indication falls outside of the Strattice Reconstructive Tissue Matrix's intended use because surgical mesh has not been cleared or approved for use in breast reconstructive surgery applications. The specific breast reconstructive surgery indication is a major change in the intended use of a surgical mesh cleared with a general soft tissue reinforcement indication regulated by 21 CFR 878.3300.

For a device requiring premarket approval, the notification required by section 510(k) of the Act, 2 U.S.C. § 360(k), is deemed satisfied when a PMA is pending before the agency. 21 CFR 807.81 (b). The kind of information that your firm needs to submit in order to obtain approval or clearance for the device is described on the Internet at http://www.fda.gov/MedicalDevices/DeviceRegula tionandGuidance/HowtoMarketYourDevice/default.htm (http://www.fda.gov/MedicalDevic-es/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm). The FDA will evaluate the information that your firm submits and decide whether the product may be legally marketed.

Our office requests that LifeCell Corporation immediately cease activities that result in the misbranding or adulteration of the Strattice Reconstructive Tissue Matrix, such as the commercial distribution of the device for the uses discussed above.

http://www.fda.gov/iceci/enforcementactions/warningletters/2015/ucm449737.htm 10/11/2

"Specifically, the Strattice Reconstructive Tissue Matrix was cleared under K082176 as 'LTM-BPS Surgical Mesh' for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes which require the use of reinforcing or bridging material to obtain the desired surgical outcome. The implant is intended for reinforcement of soft tissues in plastic and reconstructive surgery. … However, your firm's promotion of the Strattice Reconstructive Tissue Matrix provides evidence that the device is intended for breast reconstructive surgery applications, which would constitute a major change or modification to its intended use, for which your firm lacks clearance or approval."

Promotion Using Social Media

Social Media Regulatory Challenges

- Statute and regulations drafted for traditional print materials

(l)(1) Advertisements subject to section 502(n) of the act include advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems.

(2) Brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and references published (for example, the "Physicians Desk Reference") for use by medical practitioners, pharmacists, or nurses, containing drug information

- Interacting on social media:
  - Same general rules apply – cannot promote via social media what would not be appropriate in other forums
  - Company responsible for content that it adopts or endorses through social media, e.g., liking, reposting
- FDA enforcement with respect to social media has ramped up in recent years

Responsibility for Social Media Content

2014 “Misinformation” Draft Guidance clarifies the types of content for which a company is “responsible”

A firm is responsible for communications that are owned, controlled, created, “influenced,” or affirmatively adopted or endorsed by the firm.

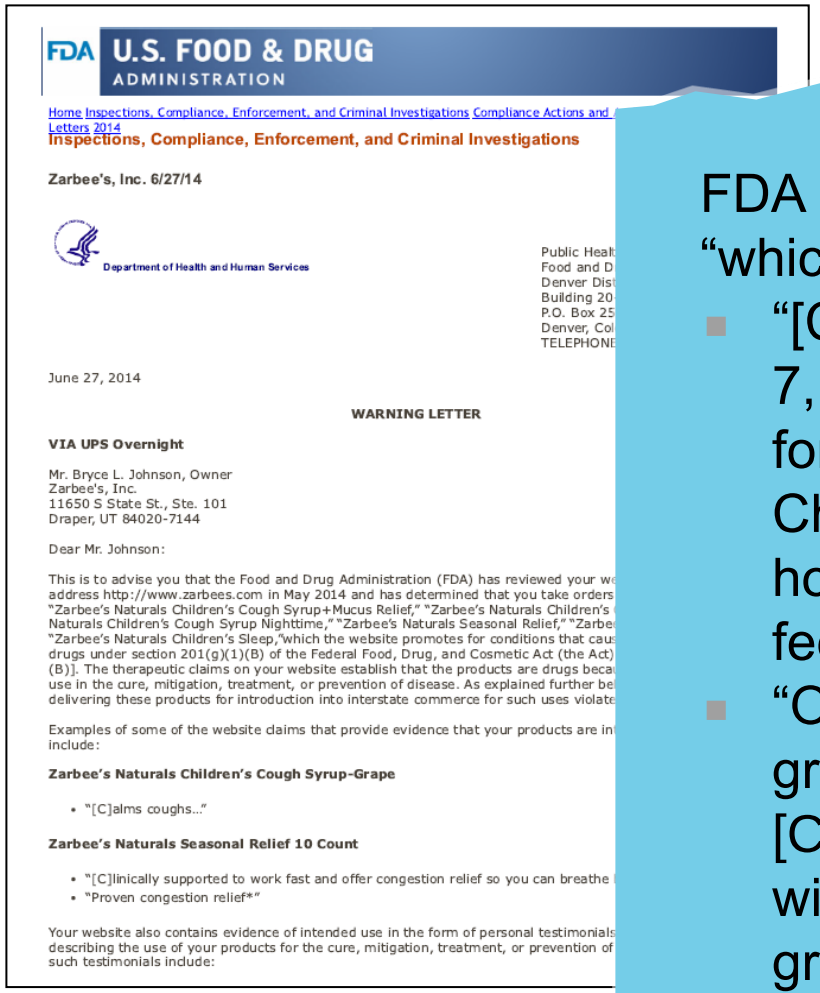
- Internet and social-media content made by the company or its agent
- Discussion hosted on company website with comments moderated by company

A firm is not responsible for user-generated content (UGC) that is independent

Even if posted on company owned site, if firm has no control over content

Content for which the company is responsible must comply with regulatory requirements

Warning Letter: Adoption of Inappropriate Statements



FDA U.S. FOOD & DRUG ADMINISTRATION

Home Inspections, Compliance, Enforcement, and Criminal Investigations Compliance Actions and
Letters 2014

Inspections, Compliance, Enforcement, and Criminal Investigations

Zarbee's, Inc. 6/27/14

Department of Health and Human Services

Public Healt
Food and D
Denver Dist
Building 20
P.O. Box 25
Denver, Col
TELEPHONE

June 27, 2014

WARNING LETTER

VIA UPS Overnight

Mr. Bryce L. Johnson, Owner
Zarbee's, Inc.
11650 S State St., Ste. 101
Draper, UT 84020-7144

Dear Mr. Johnson:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your we
address http://www.zarbees.com in May 2014 and has determined that you take orders
"Zarbee's Naturals Children's Cough Syrup+Mucus Relief," "Zarbee's Naturals Children's
Naturals Children's Cough Syrup Nighttime," "Zarbee's Naturals Seasonal Relief," "Zarbe
"Zarbee's Naturals Children's Sleep,"which the website promotes for conditions that caus
drugs under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act)
(B)]. The therapeutic claims on your website establish that the products are drugs beca
use in the cure, mitigation, treatment, or prevention of disease. As explained further be
delivering these products for introduction into interstate commerce for such uses violate

Examples of some of the website claims that provide evidence that your products are in
include:

Zarbee's Naturals Children's Cough Syrup-Grape

- "[C]alms coughs…"

Zarbee's Naturals Seasonal Relief 10 Count

- "[C]linically supported to work fast and offer congestion relief so you can breathe
- "Proven congestion relief*"

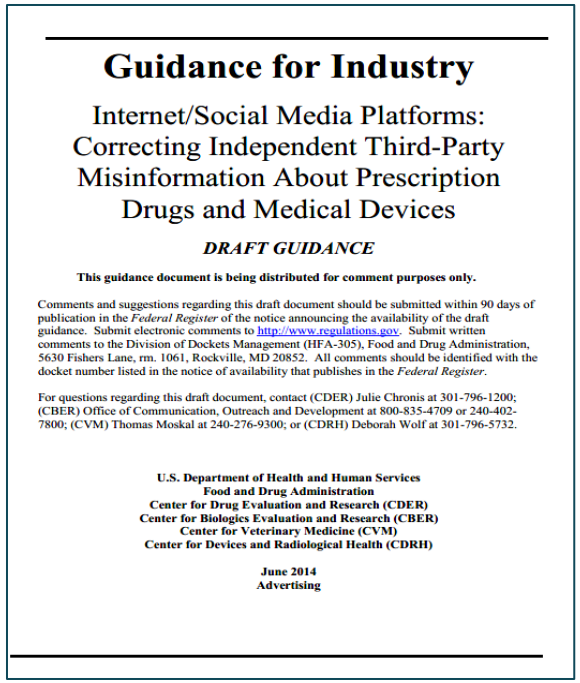
Your website also contains evidence of intended use in the form of personal testimonials
describing the use of your products for the cure, mitigation, treatment, or prevention of
such testimonials include:

FDA cited user testimonials on company's Facebook page "which are endorsed or promoted by [the company]" including:

- "[Company] 'liked' the following comment made on January 7, 2014: 'I've been battling either bronchitis or pneumonia for the last 18 days and have tried everything…your Children's Cough Syrup and mucus relief got rid of…my hoarsness [sic]…[m]y throat and chest are beginning to feel so much better…'"
- "On January 6, 2014: '…It is the best thing for my granddaughters bronchitis.' On January 7, 2014: [Company] commented 'Vivian, we switched that item out with our Children's Nighttime Cough Syrup which works great!!!' on this claim."

Correcting Third-Party "Misinformation"

- A firm may choose to correct third party misinformation, but it is not required to do so
- Corrective information should be:
  - Limited and tailored to correcting the misinformation
  - Non-promotional in tone and presentation
  - Accompanied by FDA-approved labeling
  - Accurate and supported by appropriate evidence
  - Made by firm representative with disclosure of affiliation
- Firms should clearly identify the particular piece of misinformation and the portion of the forum it is correcting



Guidance for Industry

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

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

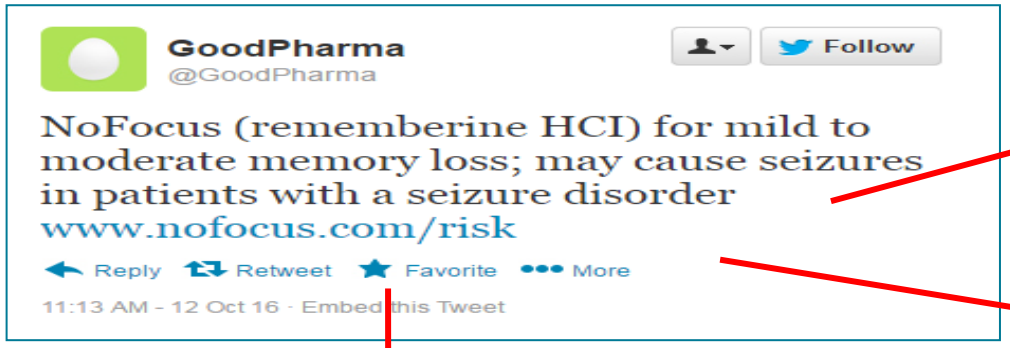
For questions regarding this draft document, contact (CDER) Julie Chronis at 301-796-1200; (CBER) Office of Communication, Outreach and Development at 800-835-4709 or 240-402-7800; (CVM) Thomas Moskal at 240-276-9300; or (CDRH) Deborah Wolf at 301-796-5732.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Veterinary Medicine (CVM)
Center for Devices and Radiological Health (CDRH)

June 2014
Advertising

“Character-Space-Limited Platforms” Guidance

- Draft guidance applies to platforms like Twitter and “sponsored links” on search engines (Google, Yahoo) that have limited space
- Does not cover product websites, online banners, or reminder advertising



Benefit info must be accurate and non-misleading

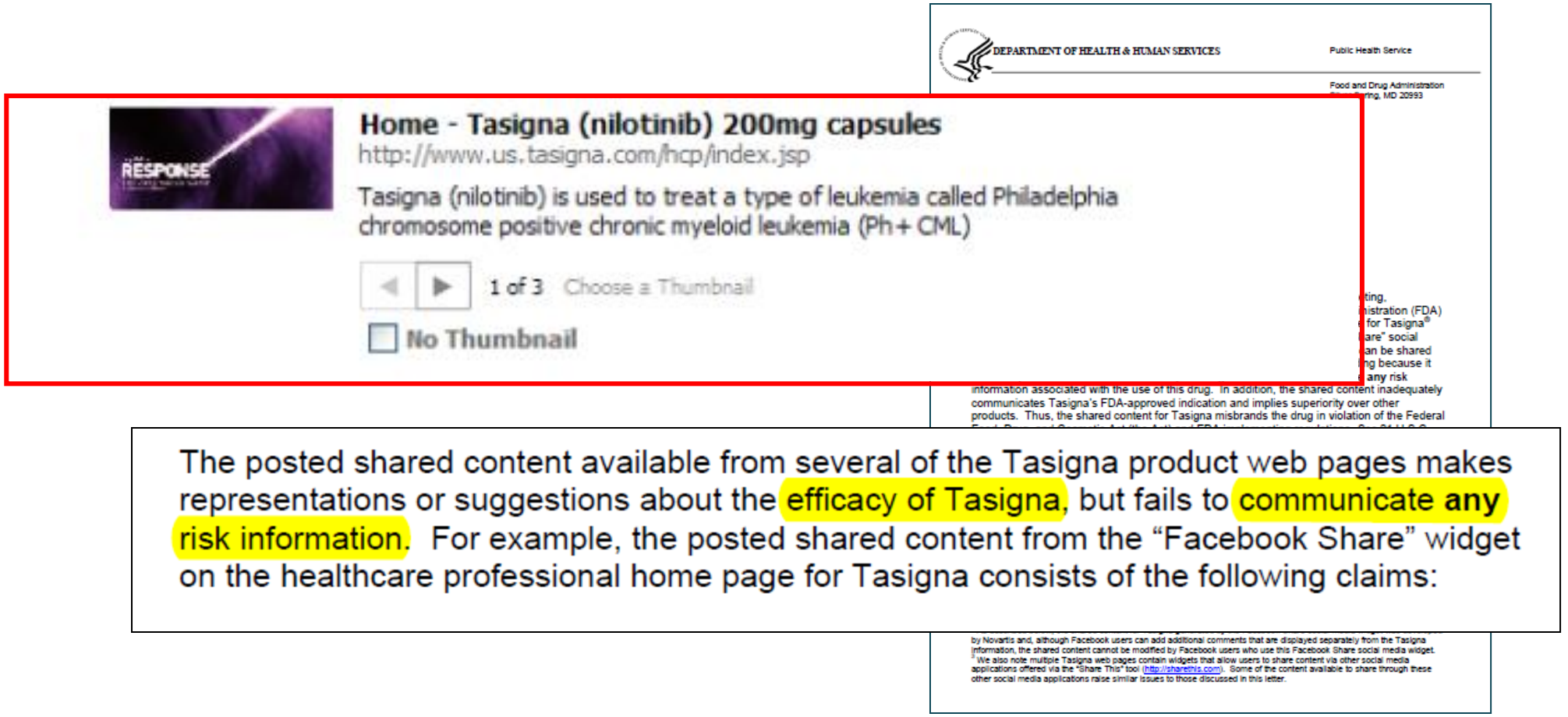
Include both benefit and most serious risks within the communication, in comparably prominent manner

Direct hyperlink to more complete discussion of risk information: link to a safety info page, not a promotional page

- Products with complex indications or extensive serious risks may not be able to use such platforms in “meaningful ways”

Warning Letter: Lack of Safety Information

- Presentation of risk information in Facebook share widget



Testimonials and Endorsements

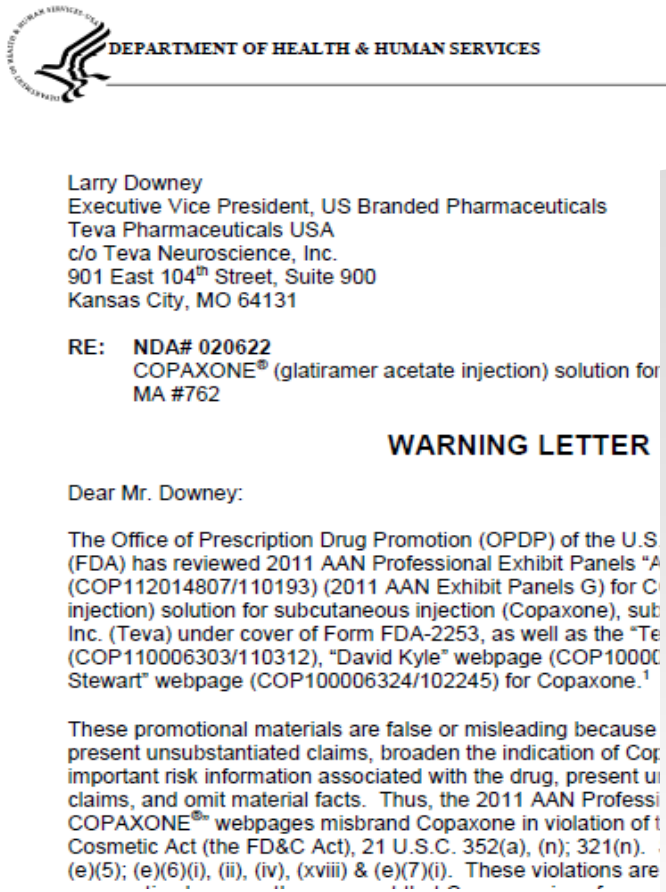
Testimonials/Endorsements

- FDA is usually skeptical of testimonials and endorsements
  - Testimonials are often "inherently misleading" and "not balanced" because "only patients [and physicians] with good outcomes . . . have testimonials"
    (Deborah Wolf, CDRH)
- Testimonials should not go beyond the safety and efficacy demonstrated in labeling
  - Portrayals should reflect the typical patient/user experience
  - Claims should not be exaggerated
  - Claims should be balanced and disclose risks of the product
- Disclaimers like "individual results may vary" or "risks include…." are <u>not</u> sufficient to mitigate the misleading nature of testimonials

Testimonials/Endorsements

- In May 2015, FTC issued updated guidelines regarding testimonials/endorsements
  - "Testimonials claiming specific results usually will be interpreted to mean that the endorser's experience reflects what others can also expect. Statements like 'Results not typical' or 'Individual results may vary' won't change that interpretation."
- That leaves advertisers with two choices:
  - Have adequate proof to back up the claim that the results shown in the ad are typical, or
  - Clearly and conspicuously disclose the generally expected performance in the circumstances shown in the ad

Warning Letter: Inappropriate Patient Testimonial



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Larry Downey
Executive Vice President, US Branded Pharmaceuticals
Teva Pharmaceuticals USA
c/o Teva Neuroscience, Inc.
901 East 104th Street, Suite 900
Kansas City, MO 64131

RE: **NDA# 020622**
COPAXONE® (glatiramer acetate injection) solution for
MA #762

WARNING LETTER

Dear Mr. Downey:

The Office of Prescription Drug Promotion (OPDP) of the U.S
(FDA) has reviewed 2011 AAN Professional Exhibit Panels "A
(COP112014807/110193) (2011 AAN Exhibit Panels G) for C
injection) solution for subcutaneous injection (Copaxone), sub
Inc. (Teva) under cover of Form FDA-2253, as well as the "Te
(COP110006303/110312), "David Kyle" webpage (COP10000
Stewart" webpage (COP100006324/102245) for Copaxone.[1]

These promotional materials are false or misleading because
present unsubstantiated claims, broaden the indication of Cop
important risk information associated with the drug, present u
claims, and omit material facts. Thus, the 2011 AAN Professi
COPAXONE® webpages misbrand Copaxone in violation of t
Cosmetic Act (the FD&C Act), 21 U.S.C. 352(a), (n); 321(n).
(e)(5); (e)(6)(i), (ii), (iv), (xviii) & (e)(7)(i). These violations are

"…the patient testimonials misleadingly broaden the indication and overstate the efficacy of Copaxone. . . . . Copaxone is **not** indicated for slowing, preventing or reversing physical disability associated with RRMS. Moreover, FDA is not aware of substantial evidence or substantial clinical experience supporting the implication that Copaxone treatment will result in the magnitude of effects as described in the above patient testimonials. . . . . The personal experiences of 'Team Copaxone' patients . . . do not constitute substantial evidence to support such claims and presentations. If you have data to support these claims, please submit them to FDA for review."

Warning Letter: Influencers Held to Same Standard

- ☑ Efficacy claims
- ☑ Important Safety Information
- ☒ Risk information
- ☒ Material facts

Bottom Line: post implies that product is safer than has been demonstrated

FDA-Mandated Corrective Ad

kimkardashian FOLLOW

382k likes 1d

kimkardashian #CorrectiveAd I guess you saw the attention my last #morningsickness post received. The FDA has told Duchesnay, Inc., that my last post about Diclegis (doxylamine succinate and pyridoxine HCl) was incomplete because it did not include any risk information or important limitations of use for Diclegis. A link to this information accompanied the post, but this didn't meet FDA requirements. So, I'm re-posting and sharing this important information about Diclegis. For US Residents Only.
Diclegis is a prescription medicine used to treat nausea and vomiting of pregnancy in women who have not improved with change in diet or other non-medicine treatments.
Limitation of Use: Diclegis has not been studied in women with hyperemesis gravidarum.

Log in to like or comment.

#CorrectiveAd

Original post deleted and new post complied with FDA's corrective advertising requirements, including Important Safety Information

Endorsements: Experts

- Whenever an advertisement represents, directly or by implication, that the endorser is an expert, the endorser must actually have such expertise.
- Endorsement must be supported by an actual evaluation of the product
  - Evaluation must have been at least as extensive as someone with the same degree of expertise would normally need to conduct in order to support the conclusions presented in the endorsement.

Warning Letter to manufacturer of a vascular hemostasis device

"[A] testimonial by one of the physicians on your web site . . states, *Our overall complication rates (major and minor) with VasoSeal have been extremely low--1.25%.* These statements essentially contradict the complication rates identified in the approved labeling and approved instructions for use."

Material Connections

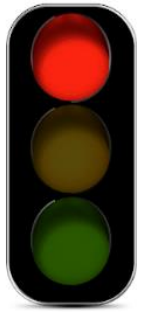
- "Material connections" between endorser and company must be clearly and conspicuously disclosed as part of endorsement
- Material connection could be:
  - Monetary payment or financial arrangements (e.g., "ambassadors")
  - Free product with expectation that endorser will discuss product
- Material connections also impact whether company is "responsible" for content of testimonial or endorsement
  - Company is responsible for content controlled or "influenced" by the firm (e.g., via financial arrangements)
  - Company is also responsible for content it adopts of endorses (e.g., reposts, retweets, likes, etc.)

Off-Label Communications

The "Off-Label" Paradigm

Physicians may use cleared/approved drugs and devices for unapproved/uncleared uses

- The approved labeling may lag behind medical science
- Off-label use may be accepted medical practice, supported by literature, and reimbursed by federal health care programs



BUT, companies may not promote an off-label use.

- Off-label promotion can trigger FDA Warning Letters, DOJ investigations, settlements, collateral lawsuits, and criminal prosecutions
- In FDA's traditional view, it does not matter if the off-label information is truthful and accurate, or whether the off-label use is a safe and effective use of the drug or device – if it is off-label promotion, it can trigger enforcement

Traditional Areas of Communications re Unapproved Uses

Answering Questions

May respond to "unsolicited" requests, even if the response requires the company to share off-label information (Draft Guidance, Dec. 2011):

- Initiated by persons that are completely independent of the company
- Not "prompted" in any way
- Public v. Private unsolicited requests

Questions?