Food and Drug Law Institute
Introduction to Medical Device Law and Regulation:
Promotion and Advertising
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James R. Ravitz, Esq.
jravitz@wsgr.com
202-973-8804

Georgia C. Ravitz, Esq.
gravitz@wsgr.com
202-973-8806

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James R. Ravitz, Esq.

Jamie Ravitz is a partner in the Washington, D.C., office of Wilson Sonsini Goodrich & Rosati, where he is a member of the firm's U.S. Food and Drug Administration (FDA), healthcare, and consumer products compliance practice.

Jamie regularly works with manufacturers and distributors of products that are extensively regulated by the FDA, such as medical devices (including digital applications), drugs, biologics, food, cannabis, dietary supplements, and cosmetic products. He has worked with clients at all points in the product life cycle, from providing strategic regulatory approval direction at the product concept stage through post-marketing issues including product marketing, labeling, advertising, and recalls and crisis matters.

A substantial part of Jamie's practice includes counseling manufacturers and providers on healthcare compliance matters, including broad-based fraud and abuse laws, the Anti-Kickback Statute, the False Claims Act, the Sunshine Act, patient privacy statutes, and product reimbursement. He has worked with clients on numerous internal investigations and responses to Office of Inspector General (OIG) and U.S. Department of Justice (DOJ) subpoenas, and has assisted in the defense of qui tam whistleblower suits alleging violations of the False Claims Act.

Jamie frequently works in a transaction support role, where he provides subject matter expertise in private equity and strategic M&A matters, as well as capital markets transactions. He speaks and writes frequently on topics related to the life sciences industry.

Prior to joining the firm, Jamie was a partner in the Washington, D.C., office of Arent Fox, where he led the FDA/healthcare life sciences practice. Earlier in his career, he was an associate at Sonnenschein Nath & Rosenthal.

Georgia C. Ravitz, Esq.

Georgia Ravitz is a partner in the life sciences practice of Wilson Sonsini Goodrich & Rosati, where she specializes in FDA regulatory, healthcare, and consumer products innovation and compliance. In particular, she focuses on food and drug law and regulatory policy governing the regulation and promotion of medical devices, pharmaceuticals (including OTCs), health and beauty aids (cosmetics), dietary supplements, vitamins, food and agribusiness, tobacco and e-cigarettes, cannabis, and a wide variety of consumer goods and emerging consumer technologies. She counsels U.S. and foreign manufacturers, distributors, retailers, and importers of regulated products in all phases of their product lifecycle, from innovation through product commercialization and ongoing post-market compliance.

Prior to joining the firm, Georgia was a senior partner in the FDA and advertising practices of Arent Fox in Washington, D.C., where she led the firm's consumer product safety practice. She is a frequent speaker at conferences and events, and a regular contributor to leading trade and consumer media outlets.

Overview

- FDA is the principal agency with authority over pharmaceutical, biologic, and medical device labeling, promotion and advertising.

- FDA's authority primarily flows from the Federal Food, Drug, and Cosmetic Act (FDCA).

- The FDCA and the regulations and guidance documents issued by FDA to implement and interpret the Act, governs the labeling, promotion and advertising of pharmaceutical drug and medical device products

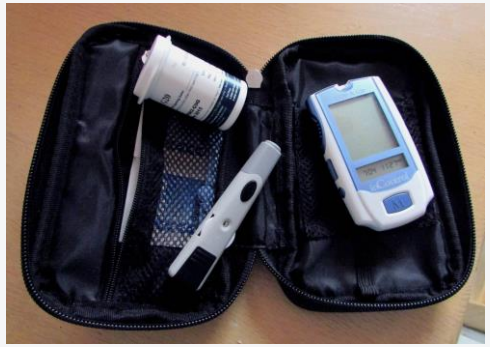
    - includes prescription drugs and devices, over-the-counter (OTC) drugs and devices, vaccines, blood products and other biological drug products.

Scope of Authority over Medical Devices

- Medical devices sold in the US are generally regulated by two FDA Centers: the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER).

CDRH → responsible for regulating firms that manufacture, repackage, re-label, sterilize, distribute, import and/or export medical devices.

CBER → regulates some medical devices used in the collection of whole blood and other blood products. E.g., cell separation devices, blood collection containers and HIV screening tests that are used to prepare blood products or to ensure the safety of the blood supply.



What is a Medical Device?

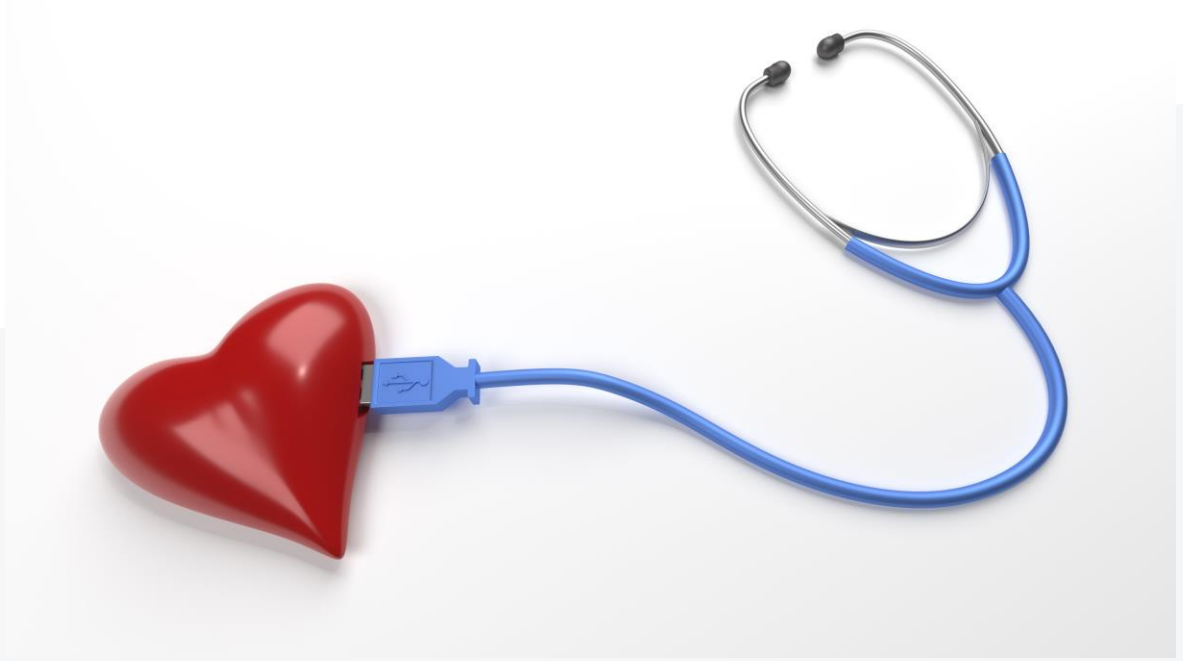
"Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory that:

- is recognized in the official National Formulary, the United States Pharmacopeia, or any supplement to them;
- **is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease** in man or other animals; or
- **is intended to affect the structure or any function of the body** of man or other animals; and
- does not achieve its primary intended purposes through chemical action within or on the body of man or other animals, and is not dependent upon being metabolized for the achievement of its primary intended purposes.

Lawful Medical Device Promotion

- Lawful promotion complies with applicable FDA regulations and guidance.

- Pursuant to FDA's general device labeling requirements, the labels of all medical devices are required to contain the name and place of business of the manufacturer, packager or distributor.



Label and Labeling

- The FDCA governs the labeling of medical devices in the United States, as well as advertisements for restricted medical devices.

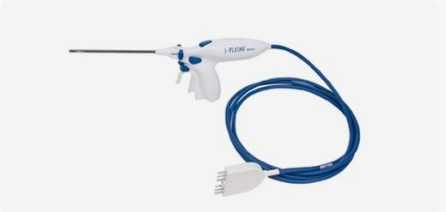
- The term “labeling” is deemed to include a broad spectrum of materials that might otherwise be viewed as advertising as opposed to labeling.

- The term has been interpreted in a very broad way and has come to include any written, printed or graphic material that

  - supplements or explains the product;

  - is disseminated by the manufacturer in a commercial context; and,

  - Accompanies the product to reach the intended audience.



Definition of Accompanying

- Is interpreted liberally to mean more than physical association with the product
- Extends to posters, tags, pamphlets, circulars, booklets, brochures, instruction books, direction sheets, fillers, etc., depending how they are used
- Includes labeling that is brought together with the device after shipment or delivery for shipment in interstate commerce.

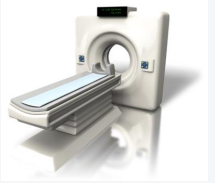
Advertising and Promotion

- Device labeling includes brochures, billboards, mailings, posters, “Dear Doctor” letters, trade show display materials, and website materials.

- CDRH applies similar principles to promotional materials for medical devices as it does traditional labeling. Virtually all promotional materials are viewed by the FDA as labeling or promotional labeling.

- Reprints of medical articles distributed with a device are categorized as promotional labeling.

- Promotional materials that are not written, printed or graphic, and use oral, audio and/or video representations to promote the device are considered advertising or promotion.



False and Misleading Labeling and Promotion

- FDA (and FTC) require labeling and advertising/promotion to be truthful and not misleading based on affirmative representations. As a general rule, product claims should be based on reliable scientific data, which may require the use of well-controlled clinical trials.

- Failure to reveal facts material to the representations made or consequences that may result from the use of the product, that could render the product misbranded.

- Information about the use, benefits and risks stated in labeling or advertising must be consistent with the device's approved or cleared labeling. Labeling and advertising must present a fair balance of information relating to product risk and effectiveness.

Misbranded Medical Devices

Non-compliant labeling and advertising material can render a device misbranded (or even adulterated) under the FDCA. E.g.:

- the labeling is false or misleading in any particular way;
- the device packaging label does not contain:
    - the name and place of business of the manufacturer, packer or distributor; and
    - an accurate statement of the quantity of the contents;
- information required to be on the device labeling or label is not conspicuous or is not clear.

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Examples of misleading labeling include:

- Ambiguity, half-truths, and trade puffery
- Expressions of opinion or subjective statements
- Failure to reveal material facts, consequences that may result from use, or the existence of difference of opinion

Examples of other objectionable labeling practices include:

- Deceptive pictorial matter
- Misleading testimonials
- Misleading list of parts or components
- Use of brand or trade names instead of "established names"

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Intended Use and Off-Label Promotion

- An off-label claim is a claim or statement about an FDA- regulated product that represents or implies that the product is useful in ways that are not approved or cleared by the FDA.

- Manufacturers and distributors of FDA-regulated medical products may not promote their products for “off-label” uses.

    - This includes disseminating materials that discuss such uses (either directly or impliedly).

- FDA recognizes that off-label uses of drugs and devices occur and that such uses have an important place in the practice of medicine, but promoting for such use is strictly prohibited.

Subjective and Objective Intent

- An advertiser's Intent is determined by plain statements and facts/circumstances surrounding the advertising/promotion.
- Intended use of a device is based upon both the subjective intent, rather, the "objective intent" of the advertiser
- Objective intent can be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives.
- Intended use can be established if the advertiser is aware that the product is being offered and used for a purpose for which it is neither labeled nor advertised. It is a totality of circumstances analysis.

Fair Balance of Risk Information

- Information about the use, benefits and risks stated in labeling or advertising must be consistent with the device's approved or cleared labeling. Labeling and advertising must present a fair balance of information relating to product risk and effectiveness.

- Risk information is critical to fair balance.
- Insufficient disclosure of risk information means the device promotion is not fairly balanced and misbrands the device.
- FDA Guidance extensively discusses how to present risk information in promotional material directed to patients, consumers and healthcare professionals.
    - Provides FDA's views on medical device promotional pieces to determine whether they adequately present risk information.

Factors in Determining Adequacy of Risk Information

The FDA also identifies various factors and considerations in determining the adequacy of risk information presentation. The General Considerations section of the Risk Information Draft Guidance mentions the following:

- Consistent Use of Language Appropriate for Target Audience
- Use of Signals
- Framing Risk Information
- Hierarchy of Risk Information

Additional Considerations Regarding Content

The Content Considerations section of the Guidance identifies the following factors that may influence whether risk information is adequately presented:

- Quantity
- Materiality and Comprehensiveness

Advertising – Legal Framework

- Not defined in the FFDCA
- FDA likes to treat advertising as labeling
- Consider social media, websites, magazines, radio and TV ads
- FTC has jurisdiction over device advertising other than for restricted devices

FTC's Role in Device Advertising and Promotion

- The Federal Trade Commission Act gives the FTC broad authority over all advertising and promotional material – including FDA-regulated products.

- FTC regulates the advertising (not labeling) of many medical devices under the FTC Act which prohibits false and misleading advertising.

- Memorandum of Understanding between the FDA and the FTC:

    - FTC has primary authority over the advertising of foods, dietary supplements, OTC drugs and non-restricted medical devices,

    - FDA has primary authority over the labeling of those products. The FDA retains authority over all prescription product promotion.

- FDA has statutory authority to regulate advertising of restricted devices (including prescription-only devices).

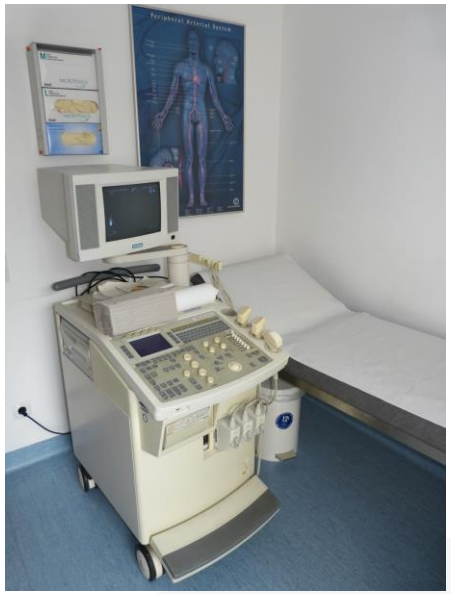
FTC Regulation of Advertising

- FTC has jurisdiction over advertising for a non-restricted device
- FTC applies three requirements
    - Adequate substantiation
    - No deception
    - Fairness

Claim Substantiation

- Refers to the evidence needed to support a claim regarding some feature or performance of the device
- Must support both express and implied claims
- FDA guidance not yet developed on device claim substantiation

FTC Factors for Adequate Substantiation



- Type of product
- Type of claim
- Benefits of a truthful claim
- Cost/feasibility of developing substantiation for the claim
- Consequences of a false claim
- Amount of substantiation that experts in the field believe is reasonable

Comparative claims

- Claims that compare the device to another device.
- FDA considers them inherently misleading unless
  - Such claims are supported by sound scientific data, usually a rigorous study that directly compares the devices.
- FTC does not have that same predisposition, instead favoring useful comparisons
  - But likewise requires rigorous scientific evidence, again a study or studies comparing the devices.

Establishment claims

- Claims that declare or even suggest that a device's superiority has been scientifically proven.
- Both FDA and FTC require the company to have at least the level of evidence stated or implied in the claim.
    - There is also a baseline of support required
    - Studies must be able to withstand criticism

Unsolicited Requests

- When may off-label information be provided?
    - In response to an unsolicited request of a health care provider
- Best Practices: Unsolicited Requests

Off-Label Promotion

- When is it acceptable
- Unsolicited requests for information
- Solicited requests

Recordkeeping for Requests for Information

A firm should maintain the following records:

- The nature of the request for information, including the name, address and affiliation of the requestor
- Records regarding the information provided to the requestor
- Any follow-up inquiries or questions from the requestor

Investor Communications

- What legal standard applies to information regarding investigational uses?

Website Advertising and Promotion

- Who regulates medical device website content?
  - FTC and FDA
- Is a website labeling or advertising?
  - FDA considers written, printed, or graphic material placed on a manufacturer's or own label distributor's Internet website to be labeling.
  - We suggest that you review your current labeling, including … any internet advertising ….
  - FDA uses conduct prohibited in any medium as a basis of enforcement actions related to websites

Website Advertising and Promotion

- Ways to minimize risk for websites

Trade Shows

- What standards apply to information disseminated at trade shows?
    - Labeling regulations apply

- FDA frequently cites companies for their trade show activities.
- Procedures to minimize risk for disseminating information at trade shows

Scientific Meetings

- Controlled- speakers under the control of the sponsor (e.g., employees, consultants)
    - Investigator meetings
    - Speaker training
    - Trade show booths
- Supported - speakers are not under the sponsor's control but sponsor provides support for the program (speakers without employment/consultant relationships with the sponsor)
    - Sponsored CME

Controlled or Supported Meeting Communications

- Regulated as promotional material
- Remarks should:
  - Be consistent with intended use
  - Conform to rules applicable to unsolicited requests
- Extent of speaker's independence

Trends in Enforcement

- FDA focus is on low hanging fruit
  - Trade show exhibits and booths
  - Website advertising and links
  - Media (broadcast, print) advertising
  - Promotional materials
  - Connection of off-label promotion to Medicaid or Medicare reimbursement claims

Risks in Promotional Interactions with Physicians

Applicable law

- Federal Anti-kickback statute
- Fraud and Abuse provisions of the Social Security Act (Medicare/Medicaid statute)
- Federal False Claims Act
- State Anti-kickback statutes
- State False Claims Acts
- State statutes requiring disclosure of gifts to prescribers

WARNING LETTER TO VIVERA PHARMACEUTICALS

Date: July 26, 2021

RE: Adulterated/Misbranded Products

FDA has reviewed your websites at the Internet addresses and observed that your websites offered a "COVxRDA Saliva Antigen Test" and a "COVx-RDA Nasal Antigen Test" for sale in the US. United States.

Based on our review, the COVxRDA Antigen Test Kits are intended for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19[1] in people, and thus, are devices under section 201(h) of the Federal Food, Drug, and Cosmetic Act.

The COVxRDA Antigen Test Kits were offered for sale in the United States without marketing approval, clearance, or authorization from FDA.

Accordingly, the COVxRDA Antigen Test Kits are adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have approved applications for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a) and also misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o).

Within 48 hours, please send an email to COVID-19-Task-Force-CDRH@fda.hhs.gov describing the specific steps you have taken to prevent future violations.

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/vivera-pharmaceuticals-inc-614412-07262021

WARNING LETTER TO OWLET BABY CARE

Date: October 5, 2021

Re: Owlet Smart Sock Family (version/generation 1, 2, 3, Smart Sock Plus

- **FDA has learned that your firm is marketing Owlet Smart Socks in the United States without marketing clearance or approval, in violation of the Federal Food, Drug, and Cosmetic Act (the Act).**
- **Under section 201(h) of the Act, 21 U.S.C. § 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body.**
- **Products that measure blood oxygen saturation and pulse rate are devices when they are intended to identify (diagnose) desaturation and bradycardia and provide an alarm to notify users that measurements are outside preset values.**
- **Accordingly, your products are adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B.**
- **Please notify this office in writing within fifteen (15) business days from the date you receive this letter of the specific steps your firm has taken to address any violations.**

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/owlet-baby-care-inc-616354-10052021

WARNING LETTER TO AESTHETIC SYSTEMS USA

Date: May 22, 2014

RE: Vitapeel Advanced Microdermabrasion System

- **Your firm is marketing the Vitapeel Advanced Microdermabrasion System in violation of the Federal Food, Drug, and Cosmetic Act (the Act) because it is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease…**
- **The Vitapeel Advanced Microdermabrasion System is listed under 21 CFR 878.4820 (Surgical Instrument Motors and Accessories/Attachments). Devices classified under 21 CFR 878.4820 are exempt from premarket notification unless they exceed the limitations on exemption at 21 CFR 878.9(a).**
- **The Vitapeel Microdermabrasion device is intended for the following: "Reduces edema and activates blood and lymph circulation“; "Stimulates cellular renewal“;"hyperkeratinization“;"Reduces wrinkles, fine lines“; and "Fades pigment spots and evens the complexion"**
- **Because there is evidence that the Vitapeel Advanced Microdermabrasion System is intended for uses that are different from those of legally-marketed devices classified under 21 CFR 878.4820, it exceeds the limitations described in 21 CFR 878.9(a) and is not exempt from premarket notification.**
- **Please notify this office in writing within fifteen business days…**

file:///C:/Users/jhha/Downloads/Aesthetics%20Systems%20Usa%20Inc%20-%20Warning%20Letter%20-%2005222014.pdf

We’re All in This Together!

Questions?

James R. Ravitz, Esq.
jravitz@wsgr.com
202-973-8804

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