1

Introduction to the Agencies Involved in Prescription Drug and Device Labeling

The first step toward understanding the requirements for prescription drug and device labeling is having some knowledge of the agencies involved in regulating those products. Although the US Food and Drug Administration (FDA) is the most important, and certainly most prominent, regulator of prescription drugs and devices, other federal agencies support and assist FDA's efforts to ensure the safety of patients who use these products. This chapter provides a brief overview of the regulatory agencies responsible for regulating prescription drug and device labeling and enforcing those requirements.

FDA: Primary Regulator of Prescription Drugs and Devices

FDA is one of the executive agencies within the US Department of Health and Human Services (HHS). It is headed by a commissioner appointed by the president, and reports to the HHS secretary. With respect to medical products, FDA's mission has multiple elements, including: 1) ensuring the safety, efficacy and security of drug, biologic and device products to protect the public health; 2) advancing public health by helping medical product innovations get to market sooner; and 3) giving the public access to accurate scientific information necessary to use medical products safely and effectively.[1]

The *Federal Food, Drug, and Cosmetic Act* (*FD&C Act*), with its periodic amendments, is the primary source of FDA's authority, and grants the agency broad jurisdiction over prescription drugs and medical devices. Under the *FD&C Act*, a "drug" is defined as:

> articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals...articles (other than food) intended to affect the structure or any function of the body of man or other animals; [and any components thereof][2]

and a "device" is defined as:

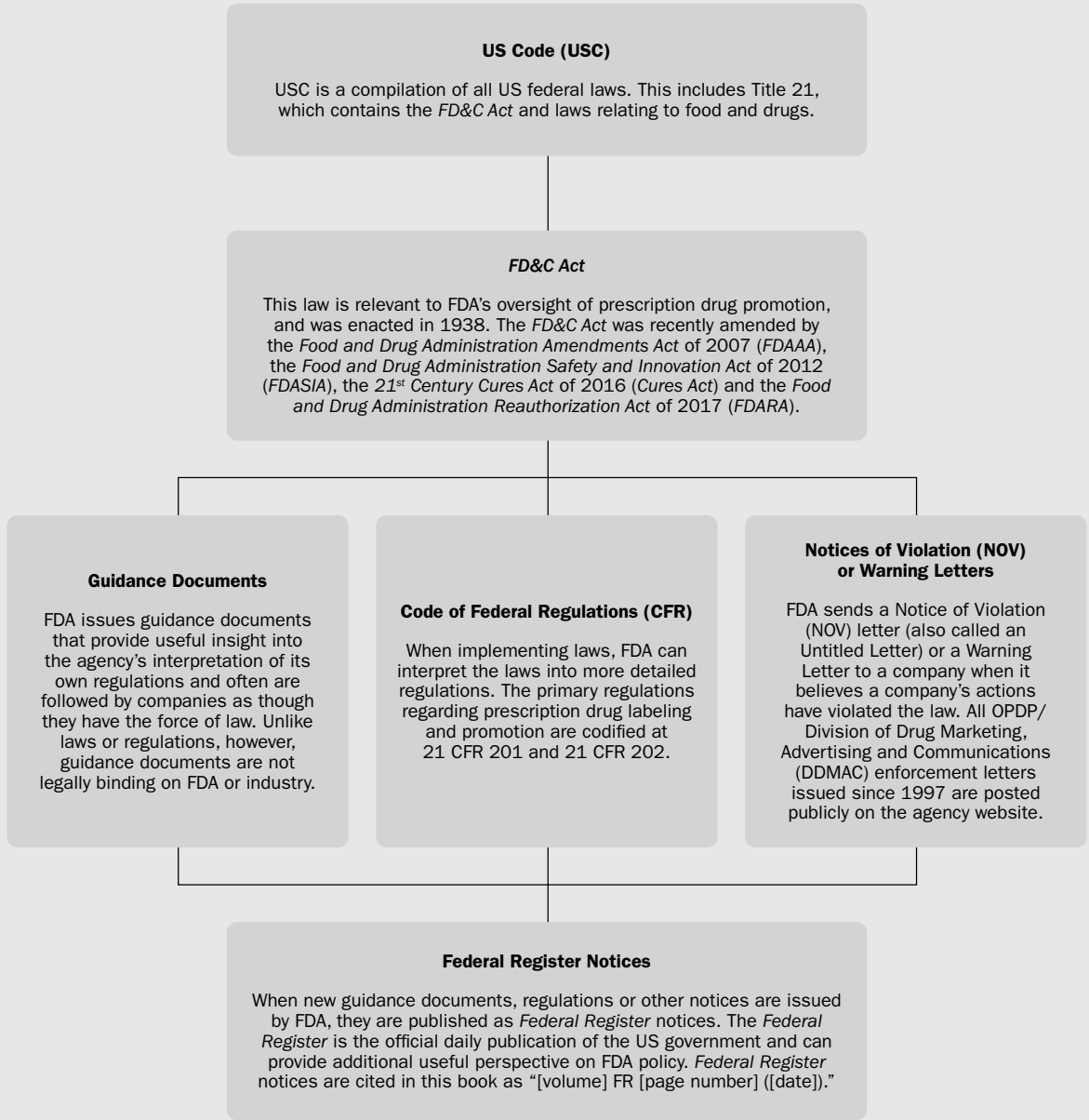
> an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is...intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or...intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action...and which is not dependent on being metabolized for the achievement of its primary intended purposes.[3]

FDA's rulemaking authority extends to many aspects of the drug and device industries, including, but not limited to, manufacturing, distribution, labeling, promotion and moving medical products or components into or out of the US. This authority allows FDA to set standards and requirements for operations relating to drugs[4] and devices,[5] which are recorded in Title 21 of the US Code of Federal Regulations (see **Sidebar 1-1**).

The *FD&C Act* enables FDA to inspect companies with drug, biologic and device operations and

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Sidebar 1-1. FDA Regulatory Basics

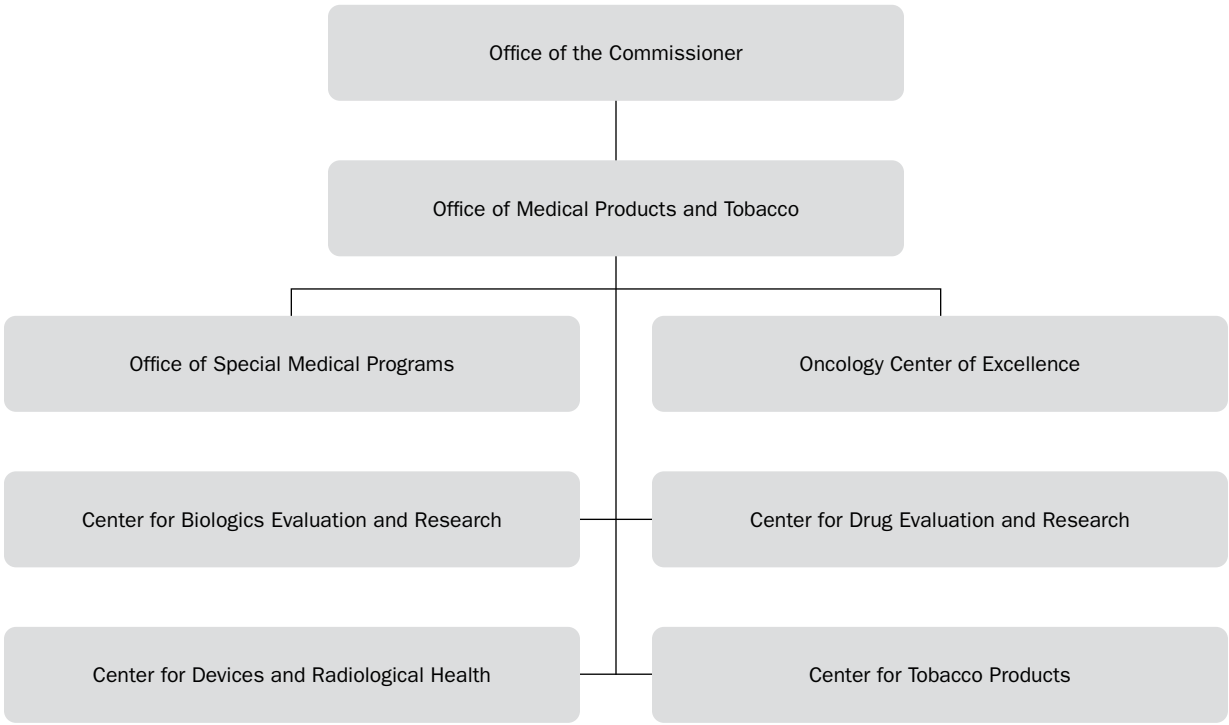


take enforcement actions if they do not comply with applicable regulations. FDA has many tools to compel compliance, including:

- Form 483—an official document an FDA investigator uses to record any observations of regulatory violations after an inspection
- Warning and Untitled Letters—written warnings that a company is in violation of an applicable regulation (or regulations) and demanding corrective actions to address the violation(s)
- Regulatory Meeting—a meeting with FDA officials to discuss how a company intends to resolve inspectional observations that have not been addressed to the agency's satisfaction
- Product Seizure—confiscation of finished product intended for sale that FDA has identified as a potential public health hazard

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Figure 1-1. Organization Chart of FDA's Office of Medical Products and Tobacco



- Preventing Review or Approval of Pending Product Applications—an administrative hold FDA places on all pending and future drug and device premarket submissions until all regulatory violations are resolved
- Injunction—a judicial order FDA obtains to shutter a manufacturing facility due to serious regulatory violations that would likely threaten public health
- Blocking Imports—an order FDA issues detaining drugs and devices intended for import at the US border or ports of entry
- Civil and Criminal Charges—FDA referral of companies accused of serious regulatory violations to the US Department of Justice for civil or criminal prosecution

Besides rule-making and performing regulatory inspections, FDA ensures prescription drugs, biologics and Class II and III medical devices' safety and effectiveness by requiring companies to submit extensive applications for review by FDA scientists prior to commercialization. If FDA approves the application, a medical product may be sold in the US; however, FDA can impose special postmarket conditions to mitigate excessive risk. For prescription drugs and therapeutic biologics, FDA requires submission of proposed indications for use, labels and labeling as part of a new drug application (NDA) or biologics license application (BLA). Manufacturers must submit all promotional labeling for prescription drugs and therapeutic biologics for review prior to publication or dissemination. FDA's regulatory oversight of prescription drug and biologics promotional materials disseminated to medical professionals and patients allows significant agency control over claims of safety and effectiveness. However, device manufacturers are not required to submit promotional labeling for FDA review at any time.

FDA's Office of Medical Products and Tobacco is subdivided into specialized centers and offices that focus on specific medical product categories (see **Figure 1-1**), and specific subdivisions are responsible for reviewing promotional materials for drugs, biologics and devices.

FDA Offices Dealing With Product Labeling

Office of Prescription Drug Promotion (OPDP)

FDA monitors the promotion of prescription drugs and therapeutic biologics through its Office of Prescription Drug Promotion (OPDP). OPDP is part of the Office

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Sidebar 1-2. Best Practices for Interacting With OPDP Reviewers

- Foster a flexible, collaborative and non-adversarial relationship.
- Set a goal for each interaction.
- Be organized and prepared.
- Listen carefully to what FDA actually says.
- Take detailed notes (consider assigning a single person to be the note taker).
- If the interaction is based on a prior communication (advisory comments or enforcement action), know the issues and the company's position.
- Follow up any requests in a timely manner.
- The company should not miss or show up late to a scheduled meeting.

of Medical Policy (OMP) in FDA's Center for Drug Evaluation and Research (CDER). OPDP is distinct from the Office of New Drugs (OND), the FDA office containing the divisions responsible for reviewing and approving new prescription drugs and therapeutic biologics, including drug labeling.

Before September 2011, OPDP was the Division of Drug Marketing, Advertising, and Communications (DDMAC). Despite the structural and name changes, the office's mission has remained the same:

> To protect the public health by assuring prescription drug information is truthful, balanced, and accurately communicated. This is accomplished through a comprehensive surveillance, enforcement, and education program, and by fostering better communication of labeling and promotional information to both healthcare professionals and consumers.[6]

OPDP's mission of protecting public health is executed via multiple actions beyond monitoring industry promotional activities and issuing letters if violations are observed. Since 2011, OPDP has prioritized its efforts to promote "voluntary compliance" by encouraging the submission of materials for advisory comment and actively developing guidance documents for industry, often based on the results of its own internal social science research activities (see **Sidebar 1-2**).

OPDP's Labeling Review Activities

A set of OPDP employees is primarily responsible for reviewing promotional materials created by pharmaceutical manufacturers. The majority of these promotional materials are submitted to OPDP by manufacturers for mandatory review "at the time of initial dissemination of the labeling and at the time of initial publication of the advertisement for a prescription drug product."[7] A completed Form FDA 2253 must accompany all mandatory submissions to OPDP. Manufacturers also may voluntarily submit draft promotional materials[8] during the launch phase (the first 120 days an FDA-approved drug or therapeutic biologic is marketed to the public), except direct-to-consumer (DTC) television advertisements, which may be submitted to OPDP for advisory comments at any time.[9]

OPDP accepts and, in fact, encourages electronic submission of materials over the internet through FDA's electronic Common Technical Document (eCTD) format. Although OPDP currently accepts both hard copy and electronic versions of promotional materials, the draft guidance, *Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs*, states that approximately two years after the final version of the guidance is published, eCTD will be the required format for promotional labeling submissions.[10] See the draft guidance for additional information on the submission process.

Launch Materials Advisory Comments

OPDP will review draft materials submitted on a voluntary basis if requested by a manufacturer, provided the manufacturer has not previously used or published the same or similar promotional claims. Due to OPDP time and resource limitations, advisory comment requests are used most often for materials with the greatest visibility: core launch materials and television advertising.

FDA defines "launch materials" as draft promotional materials associated with the approval of a new drug, indication, delivery system, formulation or route of administration.[11] Launch materials are generally a high OPDP priority based on a common-sense principle that the first impression is the most lasting. If a misleading message is conveyed when a drug is first introduced into the market, it is hard to correct. Accordingly, OPDP monitors launches closely and encourages the submission of launch materials for comment before dissemination.

FDA guidance provides the following advice about submitting launch materials for advisor comments:[12]

- "Launch" refers to the first 120 days an FDA-approved product is marketed to the public (note: this is not the date of FDA approval). Materials intended to be used after this period are not considered launch materials.
- Only "core" launch materials should be submitted for advisory comments:

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    - one comprehensive professional labeling piece (e.g., sales aid, visual aid or detail aid; or exhibit panel if there is a major conference within the launch phase) limited to 12 or fewer pages
    - one professional advertisement (e.g., journal ad) limited to four or fewer pages, not including the package insert (PI) or brief summary
    - one comprehensive DTC labeling piece (e.g., patient brochure) limited to 12 or fewer pages
    - one DTC advertisement (e.g., magazine advertisement) limited to four or fewer pages, not including the PI or brief summary
    - professional and DTC product websites (limited to 12 printed PDF pages each) or electronic sales aids that are derivatives of the comprehensive labeling piece, if one was submitted
- Other promotional materials such as slide kits, reprints and monographs are not considered core launch materials. They are a lower priority for OPDP reviewers and are not subject to the 45-day goal timeline.
- As with any request for advisory comments, the manufacturer should not use the claims in the promotional materials or similar claims while the review is pending.

OPDP tries to provide comments within 45 business days of submission, but additional time may be necessary if complex issues arise based on the content.[13] Importantly, OPDP's goal timeline of 45 days does not include any time spent consulting with the medical reviewers in the Office of New Drugs (OND) who are responsible for NDA and supplement reviews and approvals. OPDP is most likely to require a medical consult if claims in the promotional materials cannot be directly referenced to the PI. Depending on their scope, extra-label claims may significantly delay the receipt of OPDP comments. Manufacturers, therefore, must weigh the benefits of submitting these additional claims in their launch materials versus the risk of an OPDP review extending beyond 45 days.

OPDP provides metrics on the volume and percentage of completed launch reviews on its FDA-TRACK CDER Dashboard webpage on FDA's website.[14] In fiscal years 2017 and 2018, OPDP generally reviewed between 50% and 100% of core launch materials within the 45-day timeframe.[15]

The draft guidance, *Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs*, also provides information on how to submit advisory comment requests on television advertisements and other non-launch materials.[16] In general, FDA asks that a request for advisory comments on all promotional materials (including television advertisements) be submitted via an eCTD with annotated and clean versions of the proposed materials, the current FDA-approved PI, as well as a complete set of annotated references and annotated FDA-approved patient labeling (if applicable). A separate cover letter should not be submitted, but the body of the correspondence should include the specific information described in Section VI.E of the guidance, such as: a list of all promotional materials included, whether submission is for "launch" or "non-launch," whether materials are "core" or "non-core" and whether the promotional material is a television ad.[17]

Atypical Review Processes

In certain circumstances, OPDP may require the submission of promotional materials prior to dissemination.

With the passage of the *Food and Drug Administration Amendments Act* of 2007 (*FDAAA*), FDA was granted the authority to "require the submission of any television advertisement for a drug…not later than 45 days before dissemination of the television advertisement." According to its draft guidance issued in March 2012, OPDP plans to extend that pre-dissemination requirement to a significant number of television ads.[18] This issue is discussed further in Chapter 5.

FDA also has a longstanding but rarely exercised authority to require the approval of promotional materials before dissemination in cases where significant new safety information arises regarding "fatalities or serious damage" associated with use of a marketed drug.[19]

OPDP uses a diverse array of tactics to survey drug manufacturers' promotional materials. One common method is for OPDP reviewers to attend major medical meetings and pharmaceutical conventions, visiting promotional booths to observe exhibitors' practices.

Accelerated Approval/Subpart H Products

A major drug category requiring submission of materials prior to dissemination is drugs under the "accelerated approval" provisions of the *FD&C Act* and its implementing regulations.

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Sidebar 1-3. Enforcement Example: YAZ 10/2008

On 3 October 2008, OPDP sent a Warning Letter to Bayer Pharmaceuticals for two television advertisements for the oral contraceptive, YAZ (drospirenone and ethinyl estradiol).[a] At the time, YAZ was approved not only as an oral contraceptive, but also for the treatment of premenstrual dysphoric disorder (PMDD) and moderate acne in patients who were seeking birth control.

The Warning Letter stated the ads:

- misleadingly broadened the indication for the product by suggesting the drug was approved to treat PMS (as opposed to the more serious and less common condition, PMDD) and suggesting the drug was approved to treat all forms of acne (as opposed to acne of moderate severity only)
- overstated efficacy by suggesting, through visuals, that the drug will result in a complete resolution of PMDD symptoms and acne (when the drug had not been demonstrated to do so)
- minimized the risks associated with the drug by presenting distracting visuals and music in the section of the ad dedicated to risk information

Moreover, the Warning Letter requested that Bayer submit a plan for corrective action:

> "Because the violations described above are serious, we request, further, that your [response to this letter] include a comprehensive plan of action to disseminate truthful, non-misleading, and complete corrective messages about the issues discussed in this letter to the audience(s) that received the violative promotional materials."

The result of this request was a new, six-month corrective TV campaign, aimed at the same audience that had seen the original ads. During the corrective TV ad, a young woman similar to those appearing in the original ad and in a similar location speaks directly into the camera:

> "You may have seen some YAZ commercials recently that were not clear. The FDA wants us to correct a few points in those ads. YAZ is approved for pregnancy prevention. If you choose the pill for contraception, you should know that YAZ is for the treatment of premenstrual dysphoric disorder (or PMDD) and moderate acne, not for the treatment of PMS or mild acne. Unlike PMS, symptoms of PMDD are severe enough to interfere with your life. YAZ has helped many women reduce their PMDD symptoms and moderate acne; you should know that it may not work for everyone..."

[a]See also "A Birth Control Pill That Promised Too Much," *The New York Times*, 10 February 2009. *The New York Times* website. www.nytimes.com/2009/02/11/business/11pill.html. Accessed 3 September 2018.

Accelerated approval is a regulatory mechanism by which FDA may approve certain new drugs for serious and life-threatening diseases or conditions.[20] The associated regulations are found in 21 CFR Part 314, Subpart H, and products approved under this mechanism often are referred to as "Subpart H" drugs. Unlike a standard NDA approval, which requires demonstration of substantial evidence of clinical benefit, an accelerated approval can be based on an effect on a surrogate endpoint. Since the product's benefit will not have been fully elucidated at the time of approval, FDA requires Subpart H drug manufacturers to conduct additional studies postapproval.

The dissemination of promotional materials for accelerated approval products is restricted in certain ways.[21] First, all promotional materials intended for use in the first 120 days following NDA approval must be submitted for OPDP review during the preapproval period. In addition, after this initial four-month postapproval period, all promotional materials must be submitted to FDA at least 30 days prior to first use. After a certain period, FDA may determine that these submission requirements are no longer necessary and will notify the manufacturer in writing.[22]

Manufacturers of Subpart H drugs should follow the draft guidance, *Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs*, when submitting proposed promotional materials.[23]

Public Complaints and the Bad Ad Program

OPDP also regularly receives complaints from the public and from manufacturers about their competitors. OPDP has requested in public meetings that individuals submit complaints identifying the drug, the issue and the promotional piece in as much detail as possible, including an index if multiple pieces are referenced.[24] FDA's website also includes extensive educational information on prescription drug advertising, and asks consumers who encounter inaccurate or misleading advertisements to contact OPDP.[25]

While OPDP always accepted complaints from healthcare professionals and, in some cases, issued Untitled or Warning Letters based on those complaints, in May 2010, it introduced a new program to educate prescribers on how to identify and report misleading prescription drug promotion. The Truthful Prescription Drug Advertising and Promotion Program (also known as the "Bad Ad" program) was launched via presentations to prescribers and distribution of educational brochures on misleading promotion at 15 medical conferences in 2010, as well as an informational video

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on the FDA website.[26] Although FDA staff anticipated sales representatives' activities would be the primary target for Bad Ad complaints, the program has, in fact, generated letters citing a wide variety of promotional items (see **Sidebar 1-3**).

OPDP Research Activities and Development of New Policies Based on Social Science Findings

In addition to its reviewers, OPDP has dedicated staff and resources to develop policy and social science research. The studies undertaken as part of this initiative influence FDA's development of guidance documents and ensures such guidance is relevant to modern methods of product promotion (including presentation of product risk information) and to consumers' perception and understanding of promotional materials.

Some examples of OPDP social science research projects include:[27]

- Do Prescription Drug Ads Tell Consumers Enough About Benefits and Side Effects? Results from the Health Information National Trends Survey, Fourth Administration (Completed in 2015)—Using data collected by the National Cancer Institute, FDA determined that 52% of survey respondents believe DTC advertisements do not include enough information about risks, and 46% believe such advertisements do not adequately describe product benefits.
- Effect of Promotional Offers on Consumer Perceptions of Product Risks and Benefits (Completed in 2016)—OPDP investigated whether the presence of a promotional offer in DTC advertisements affects consumers' recall and perceptions of drug risks and benefits, and concluded promotional offers had no significant impact.
- Eye Tracking Study of DTC Prescription Drug Advertisement Viewing (Completed in 2016)—Using eye tracking technology, OPDP analyzed viewer perception of DTC ads and measured the impact of visual distractions. The study found that distracting elements during the major statement of risks decreased attention to superimposed text describing risk information.
- Comparative Price Information in DTC and Professional Prescription Drug Advertisements (Completed in 2017)—This study found a majority of physicians pay attention to claims comparing the prices of competitor drugs, but far fewer recognize contextual statements comparing the safety and efficacy of the same products. In the presence of price claims, the contextual statements did not affect physician perceptions on drug interchangeability, and thus, physicians may believe the lower-priced drug has lower risks.
- Animation in DTC Promotion (Ongoing)—This is a study of the effect animation in DTC ads has on consumer perception and recall of drug risk and benefit information.
- Character-Space-Limited Online Prescription Drug Communications (Ongoing)—OPDP is evaluating whether substantive risk information in sponsored link or microblog communications is effective, or whether providing a link to the full product risk information is adequate.
- Quantitative Information in DTC Television Advertisements (Ongoing)—This is a follow-up study to evaluate consumer ability to interpret and retain relatively complicated quantitative information of risks and benefits in DTC ads.

Advertising and Promotional Labeling Branch (APLB)

APLB is the branch of FDA's Center for Biologics Evaluation and Research (CBER) that enforces labeling regulations for biological products, such as vaccines, blood products and gene therapy products. Its responsibilities are essentially identical to those OPDP performs for drug products. Biologics manufacturers must submit final versions of DTC advertisements (with a completed Form FDA 2253) to APLB for review and approval prior to release, and APLB evaluates complaints that manufacturers violated promotional labeling regulations. APLB also reviews proposed proprietary names for biologic products and offers consultative reviews of biologic product labeling, PI, package inserts and medication guides. APLB may issue Warning Letters and Untitled Letters.

Center for Devices and Radiological Health (CDRH)

Unlike CDER and OPDP, which are responsible for regulating prescription drug promotion, CDRH neither reviews medical device promotional materials prior to commercialization (there is no Form 2253 equivalent for devices) nor provides advisory comments on product advertisements and promotional claims. While CDRH is charged with ensuring device manufacturers comply with labeling requirements (i.e., 21 CFR 801), it will take enforcement action only after noncompliant

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labeling is disseminated. As discussed below, the Federal Trade Commission (FTC) is responsible for enforcement against inaccurate or misleading medical device promotional materials.

However, CDRH does issue Warning Letters to entities that promote products for use as medical devices even though no premarket approval or clearance was obtained.[28] In addition, CDRH enforces regulations prohibiting promotional materials relating to devices under an investigational device exemption, discussed in Chapter 3.

The Federal Trade Commission and the Balance of Power With FDA

FTC is an independent, bipartisan federal agency whose primary mission consists of two elements: to protect consumers from deceptive and unfair business practices and to promote competition among businesses. Consistent with the authority granted in the *Federal Trade Commission Act* (*FTC Act*), FTC pursues enforcement actions against businesses that publish false and misleading advertisements for products. In fact, the *FTC Act* prohibits the dissemination of false advertisements "by any means, for the purpose of inducing… the purchase…of food, drugs, devices, services, or cosmetics" and declares false advertising is an unfair or deceptive trade practice.[29]

From this language, it appears FTC's statutory authority to enforce prohibitions against false and misleading drug and device advertising overlaps with FDA's authority—and in a way it does. FTC polices deceptive business practices related to all products sold in commerce, and FDA protects the public from adulterated and misbranded food, drugs and devices. False statements in drug or device labeling can result in product misbranding, so it is possible such matters would fall within the jurisdictions of both FTC and FDA. To avoid duplicating enforcement efforts, FTC and FDA created a Memorandum of Understanding in September 1971 that outlines each agency's authority with respect to the other. According to the memo, FTC has authority to regulate "truth or falsity of advertising" of foods, cosmetics and over-the-counter (OTC) drugs and devices, while FDA has primary authority to regulate prescription drug advertising, advertising for "restricted" medical devices (as defined by FDA) and all matters relating to food, cosmetic and OTC drug and device labeling.

Unlike FDA, FTC does not review promotional materials before a product reaches the market. Instead, FTC reviews advertisements already being disseminated or broadcast to consumers and can issue inquiries or initiate investigations if companies make false or misleading statements about the advertised product. FTC has no direct regulatory authority over the actual medical product, but it applies general principles of fair competition to ensure all product claims are properly substantiated and do not mislead consumers. For nonprescription drugs and devices, this means having adequate support from scientific research studies. Claims of medical or other benefits (e.g., relieves pain for eight hours) or claims comparing the product to a competitor (e.g., our product relieves pain for twice as long as Brand X) are common examples of advertising statements that receive FTC scrutiny if they do not have proper substantiation or omit facts that are material to ensuring the claim's truthfulness. FDA and FTC work closely together on product promotion regulations and enforcement, so manufacturers must take care to follow FTC principles when promoting medical products through testimonials, endorsements, native advertising (sponsored promotional content that looks like news articles, product reviews, entertainment and other surrounding materials) and other advertising to make sure content is truthful and not misleading. FTC may challenge any false or misleading advertisements in either administrative adjudication or US federal courts.

Council of Better Business Bureaus' National Advertising Division

The National Advertising Division (NAD) is a part of the Council of Better Business Bureaus, a private organization that is not affiliated with any branch of the US government. NAD plays a distinct independent role in policing false and misleading advertising by promoting industry self-regulation. Like FTC, NAD accepts complaints about advertisers, including OTC drug and dietary supplement manufacturers, from consumers, competing businesses and local Better Business Bureaus and reviews the implicated advertising for compliance with false advertising and consumer protection laws. It also can initiate reviews and advertising challenges on its own.

NAD reviews and decisions typically are much faster and less expensive than submitting a complaint to FTC or filing a claim in the court system. In many cases, advertisers challenged at the NAD choose to comply with the organization's recommendations to improve compliance; however, NAD does not have any power to enforce a determination that an advertiser violated the law. If NAD believes an alleged violation is particularly egregious, or if an advertiser fails to correct a confirmed violation, it will submit the case to FTC

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for review and request that the agency take appropriate enforcement action.

By its own estimate, NAD processes 150 advertising cases annually, and its decisions constitute the largest compilation of advertising decisions in the US. Because NAD legal experts apply federal advertising law standards to the challenges they review, NAD (and its appellate body, the National Advertising Review Board, or NARB) decision database is instructive and educational for all businesses who advertise their products or services in the US.

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2

Fundamental Principles for Labeling and Promotion of Prescription Medical Products

As introduced in Chapter 1, FDA approves both the label and certain types of labeling for a new prescription drug or biological product. While a layperson may not be aware of the semantic difference between the terms, "label" and "labeling" have distinct definitions under the law and regulations governing prescription drugs and biological products. The same is true for medical devices, for which the device labels and Instructions for Use (IFU) are reviewed and vetted by the agency as part of the premarket approval or clearance process.

In general, all drug, biologic and medical device labeling must not be "false or misleading," must disclose "material facts" and must include adequate warnings. **Table 2-1** provides a list of the most generally applicable regulations for the labeling of prescription drugs; similar regulations have been codified for biological products at 21 CFR Part 610 (General Biological Standards), Subpart G (610.60-610.68). A list of selected medical device labeling regulations is provided in **Table 2-2**.

"Label" vs. "Labeling"

The *FD&C Act* defines "label" as "a display of written, printed, or graphic matter upon the immediate container of any article."[1] However, the container label is only a subset of the broader legal concept of "labeling," which is defined in the act as "all labels and other written, printed, or graphic matters (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."[2] In 1948, the US Supreme Court interpreted that what Congress meant when it drafted the phrase "accompanying such article" was meant to be very broad, and that interpretation still is used today. The Supreme Court found, "[o]ne article or thing is accompanied by another when it supplements or explains it, in the manner that a committee report of the Congress accompanies a bill. No physical attachment one to the other is necessary. It is the textual relationship that is significant," *Kordel v. United States*, 335 U.S. 345, 350 (1948). In practice, therefore, product materials developed and disseminated by the product's manufacturer or distributor are nearly always considered by FDA to be "labeling" subject to the act and its implementing regulations.

Prescription drugs and biologics are exempt from a general requirement that drug labeling provide "adequate directions for use" by a layperson, as long as the labeling provides "adequate information for its use, including indications, effects, dosages, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented."[3] For prescription drugs, this requirement to provide "adequate information" for the prescriber is met by the inclusion of the FDA-approved PI, which always must be included in or within the package from which the drug is dispensed or administered.[4]

Importantly, because certain OTC drugs are approved for marketing via the NDA pathway as opposed to the more typical OTC Monograph pathway,

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