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

Guidance for Industry

REVISED DRAFT GUIDANCE

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For questions regarding this draft document contact (CDER) Julie Chronis 301-796-1200, or (CBER) Office of Communications, Outreach and Development at 800-835-4709 or 240-402-7800.

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)

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Revision 1

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Office of Communications, Division of Drug Information
Center for Drug Evaluation and Research
Food and Drug Administration
WO51, Room 2201
10903 New Hampshire Ave., Silver Spring, MD 20993-0002
Phone: 301-796-3400; Fax: 301-847-8714
druginfo@fda.hhs.gov
http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm
and
Office of Communication, Outreach and Development, HFM-40
Center for Biologics Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 71, rm. 3128,
Silver Spring, MD 20993-0002
Phone: 800-835-4709 or 240-402-7800
ocod@fda.hhs.gov
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Guidance for Industry[1]

This revised draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's or Agency's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This revised draft guidance provides recommendations on the disclosure of risk information in prescription drug product advertisements and promotional labeling in print media directed toward consumers with respect to the brief summary requirement and the requirement that adequate directions for use be included with promotional labeling.[2] The recommendations describe an alternative disclosure approach that FDA refers to as a *consumer brief summary*. This revised draft guidance does not focus on the presentation of risk information in the main body of promotional labeling or advertisements and does not apply to promotional materials directed toward health care professionals.

This revised draft guidance responds to stakeholder requests for specific guidance on the disclosure of risk information to consumers and incorporates recent social science research results (Aikin, O'Donoghue, et al. 2011). This revised draft guidance revises the draft guidance entitled *Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements* (issued January 2004).

[1] This guidance has been prepared by the Office of Prescription Drug Promotion (OPDP) in the Center for Drug Evaluation and Research (CDER) in consultation with the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration.

[2] The recommendations of this revised draft guidance also apply to biological products that are approved for marketing under section 351 of the Public Health Service Act (PHS Act). Because each biological product also meets the definition of "drug" under the Federal Food, Drug, and Cosmetic Act (FD&C Act), it is also subject to regulation under provisions of the FD&C Act applicable to drugs, as well as the regulations implementing these provisions, except that a biological product licensed under section 351 of the PHS Act is not required to have an approved new drug application under section 505 of the FD&C Act (21 U.S.C. 355). See PHS Act section 351(j) (42 U.S.C. 262(j)). References to "drugs" in this guidance therefore also include biological products that fall within the definition.

FDA's guidance documents, including this revised draft guidance, do not establish legally enforceable responsibilities. Instead, guidances describe FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

A. Legal Overview

Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Agency has responsibility for regulating the manufacture, sale, and distribution of drugs in the United States. This authority includes oversight of the labeling of drugs (21 U.S.C. 352(a)) and the advertising of prescription drugs (21 U.S.C. 352(n)).

A print advertisement[3] for a prescription drug must contain a true statement of the product's established name; quantitative composition; information in brief summary relating to side effects, contraindications, and effectiveness; and, for published direct-to-consumer advertisements, a statement encouraging consumers to report negative side effects to FDA (21 U.S.C. 352(n)). FDA implementing regulations provide further clarification on the information to include in brief summary: "a true statement of information in brief summary relating to side effects, contraindications ([to] . . . include side effects, warnings, precautions, and contraindications and include any such information under such headings as cautions, special considerations, important notes, etc.) and effectiveness" (21 CFR 202.1(e)(1)). This information "shall disclose each specific side effect and contraindication . . . contained in required, approved, or permitted labeling for the advertised drug dosage form(s) . . ." (21 CFR 202.1(e)(3)(iii)). For purposes of this guidance, the requirement under these provisions that an advertisement for a prescription drug disclose each side effect, warning, precaution, and contraindication from the labeling will be referred to as the *brief summary requirement*.

FDA also has responsibility for regulating labeling for prescription drugs, including promotional labeling. Section 201(m) of the FD&C Act defines *labeling* as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article" (21 U.S.C. 321(m)).[4] The U.S. Supreme Court has explained that the language "accompanying such article" in the "labeling" definition is interpreted broadly, to include materials that supplement or explain an article. No physical attachment between the materials and the article is necessary; rather, it is the textual relationship between the items that is significant (*Kordel v. United States*, 335 U.S. 345, 350 (1948)). FDA generally recognizes two types of labeling for drugs: (1) FDA-required labeling[5] and (2) promotional labeling.

[3] The FD&C Act does not define what constitutes an "advertisement," but FDA regulations provide several examples, including "advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems" (21 CFR 202.1(l)(1)). Broadcast advertisements, such as radio and television advertisements, are not the subject of this guidance.

[4] See also 21 CFR 1.3(a).

[5] Much FDA-required labeling is subject to FDA review and approval. For example, after drafting by the manufacturer, labeling is reviewed and approved by FDA as part of the new drug application (NDA), new animal

Promotional labeling is generally any labeling, other than the FDA-required labeling, that is devised for promotion of the product. Examples of materials that may be considered promotional labeling pieces for prescription drugs are described in 21 CFR 202.1(l)(2).

While drug labeling generally must bear "adequate directions for use" (21 U.S.C. 352(f)(1), prescription drugs are exempt from this requirement if certain conditions are met. These conditions include, among others, that "any labeling" (as defined in section 201(m) of the FD&C Act) that is "distributed by or on behalf of the manufacturer, packer, or distributor of the drug, that furnishes or purports to furnish information for use or which prescribes, recommends, or suggests a dosage for the use of the drug" contains "adequate information for such use" (21 CFR 201.100(d)). "Adequate information for such use" includes, among other things, "relevant warnings, 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 conditions for which it is advertised or represented . . ." (21 CFR 201.100(d)(1)).[6] The regulation also requires that if the article is subject to section 505 of the FD&C Act, the parts of the labeling providing such information for use are the same "in language and emphasis" as labeling approved or permitted under the provisions of section 505. (Id).

In addition, in order to be exempt from the "adequate directions for use" requirement in 21 U.S.C. 352(f), any labeling described in 21 CFR 201.100(d) must contain the "information required, and in the same format specified by" 21 CFR 201.56, 201.57, and 201.80 (21 CFR 201.100(d)(3)). Generally, the requirements in 21 CFR 201.100(d) have been fulfilled by including the full FDA-approved package insert (PI) with promotional labeling materials. For purposes of this guidance, the requirement under these provisions that a prescription drug promotional labeling piece include the information set forth in 21 CFR 201.100(d), which is generally fulfilled by inclusion of the full PI, will be referred to as the *adequate directions for use requirement*.

To fulfill the brief summary requirement, consumer-directed print advertisements for prescription drugs frequently include the complete risk-related sections of the PI (also known as the "traditional approach" or "traditional format"). To fulfill the adequate directions for use requirement for promotional labeling pieces, the full PI has generally been used. As discussed more fully in section II.B, FDA believes these approaches are not optimal for consumer-directed prescription drug print advertisements and promotional labeling pieces because many consumers lack the technical background to understand some of the information as described in the PI. Additionally, information that may be of limited use to consumers (e.g., clinical pharmacology) is included. For these reasons, if manufacturers, packers, and distributors, or anyone acting on their behalf (firms) include the appropriate information discussed in this guidance, FDA does not intend to object for failure to include each side effect from the PI in the brief summary in

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drug application (NADA), biologics license application (BLA), or premarket approval application (PMA) review (see 21 CFR 314.50(c)(2), 514.1(b)(3), and 601.2(a)). For a prescription drug to be exempted from the FD&C Act's requirement of adequate directions for use (21 U.S.C. 352(f)(1)), its FDA-required labeling must contain, among other information, information addressing product hazards and other risk information, as specified in FDA regulations (21 CFR 201.100(d)(1), (3), and 201.105(c)(1)).

[6] "Adequate information for use" under 21 CFR 201.100(d)(1) also includes indications, effects, dosages, routes, methods, and frequency and duration of administration.

consumer-directed print advertisements. Furthermore, if firms include the appropriate information discussed in this guidance, FDA does not intend to object for failure to include the entire PI to fulfill the requirements of 201.100(d) for consumer-directed promotional labeling pieces.

In other words, this revised draft guidance recommends alternative approaches firms may use to develop content that can be used to fulfill both the brief summary requirement for consumer-directed prescription drug print advertisements and the requirements in 201.100(d) in consumer-directed prescription drug print promotional labeling pieces. Suggested research-tested formats for this information are also provided in this revised draft guidance. The examples included throughout are intended to provide guidance and illustrate possible approaches; firms may use alternative approaches if these approaches satisfy the requirements of the statute and regulations.

B. Policy Overview

To provide better and more actionable information for consumers, FDA believes that the brief summary should focus on the most important risk information rather than an exhaustive list of risks and that the information should be presented in a way most likely to be understood by consumers. Thus, FDA strongly recommends against the use of the traditional approach to fulfill the brief summary requirement in consumer-directed advertisements, an approach in which risk-related sections of the PI are presented verbatim, often in small font. Because the target audience of the PI is health care providers, it is written in highly technical medical terminology, which is potentially of limited value to consumers who may not have the medical or scientific background to understand this information. In an FDA survey, few respondents reported reading half or more of the brief summary presented in the traditional format. Of those who read at least some of the brief summary, 55 percent described it as hard to read. Over 40 percent of respondents in the survey reported they do not usually read any of the brief summary in direct-to-consumer prescription drug print advertisements (Aikin, Swasy, et al. 2004).

Furthermore, the risk information in the PI sometimes includes lengthy lists of all possible adverse events. In general, FDA believes that exhaustive lists that include even minor risks detract from, and make it difficult for, consumers to comprehend and retain information about the more important risks. While remaining an important source of information for consumers, even the volume of material in excerpted sections of the PI, along with the format (i.e., a smaller font with limited white space) and the technical language, may serve to detract from consumers' comprehension of the information or from the likelihood of consumers reading the material in its entirety. Research has demonstrated that people process only a limited amount of information at one time both in general communications (Lavie 2001; Miller 1994; Shapiro 2001) and in direct-to-consumer prescription drug advertising specifically (Stotka, Rotelli, et al. 2007). Past research has shown that alternative formats for the brief summary outperform the traditional, non-consumer-friendly brief summary on measures of consumer risk comprehension (Riggs, Holdsworth, et al. 2004; Schwartz, Woloshin, et al. 2009; Stotka, Rotelli, et al. 2007; Thumma 1997).

Occasionally, sections taken from the PI to fulfill the brief summary requirement are rewritten in a manner that is meant to be more understandable to consumers. However, this approach does

not necessarily solve the problems with the traditional approach. In research conducted by FDA, participants who viewed the brief summary information in a format similar to the over-the-counter (OTC) "Drug Facts" box had better risk recall than those who viewed a traditional, but consumer-friendly, version of the brief summary. Two additional alternative formats (a Question and Answer (Q&A) format and a Highlights version from the content and format rule of 2006[7]) did not differ from the consumer-friendly traditional format on risk recall or confidence (Aikin, O'Donoghue, et al. 2011).[8]

For similar reasons that are further exacerbated by the length and complexity of the full approved professional labeling, FDA also strongly recommends against providing the full PI to satisfy the adequate directions for use requirement for consumer-directed print promotional labeling pieces for prescription drugs. While the Agency recognizes that 21 CFR 201.100(d) identifies the PI as a source for furnishing adequate directions for use, FDA believes that following the content and format recommendations in this guidance will better communicate information and help consumers make informed decisions about the medication being promoted. By adopting the content and format recommendations in this guidance, firms can also provide consumers with the same information in both advertising and promotional labeling pieces.

III. OPTIONS FOR DISCLOSING RISK INFORMATION IN CONSUMER-DIRECTED PRESCRIPTION DRUG PRINT ADVERTISEMENTS AND PROMOTIONAL LABELING

FDA does not intend to object if a firm does not include "each specific side effect and contraindication" from the PI in the brief summary in consumer-directed print advertisements (21 CFR 202.1(e)(3)(iii)), or does not supply the entire PI to fulfill the requirements in 21 CFR 201.100(d) for consumer-directed print promotional labeling pieces, so long as the firm follows the recommendations and examples in this guidance. These alternate approaches will not become a part of FDA-approved labeling.

For purposes of this guidance, in the text and examples below, the consumer-directed document recommended by FDA as an alternative to the full PI or the risk portions of the PI in consumer-directed prescription drug print promotional labeling pieces and the brief summary requirement in consumer-directed prescription drug advertisements will be referred to as the "*consumer brief summary*."

A. Language and Readability

FDA strongly encourages the use of consumer-friendly language in all consumer-directed materials. The consumer brief summary should be written in language designed for understanding by a broad target audience with various levels of literacy skills. Technical

[7] See 21 CFR 201.56, 201.57, 201.58, and 201.80.

[8] Participants who viewed the brief summary information in a format similar to the OTC Drug Facts box had better risk recall, greater confidence in their ability to perform tasks related to the brief summary, more positive attitudes toward the ad, and greater preference for the format than did those who viewed a traditional, but consumer-friendly, version of the brief summary. Participants had more positive attitudes toward the Q&A format and the Highlights format than toward the traditional format, and participants who viewed the Q&A format had more positive attitudes toward the ad than those who viewed the traditional format.

language, scientific terms, and medical jargon should be avoided. A conversational tone or language designed to engage the reader may be useful, such as in the following examples.

- "do not use if you have . . ." or "who should not use . . ." rather than "contraindications"
- "what is [drug name]" rather than "indication"
- "drowsiness" not "somnolence"
- "fainting" not "syncope"

The information in the consumer brief summary must be presented in a readable format (21 U.S.C. 352(c); 21 CFR 202.1(e)(7)(viii)). Different techniques can be used to assist consumers with comprehension of information. For example, *signals*,[9] such as headlines and subheadings, help communicate important information (Loman and Mayer 1983; Meyer 2003; Spyridakis and Standal 1987). Consumers are influenced by the layout of print information in their ability to pay attention to and process specific features of a document (Adams and Edworthy 1995; Brundage, Feldman-Stewart, et al. 2005; Frantz 1993; Morrow, Leirer, et al. 1995; Niemela and Saariluoma 2003; Wogalter and Vigilante 2003). Font size and type style can affect the readability of information (Adams and Edworthy 1995; Arditi and Cho 2005; Baker 2006; Sheedy, Subbaram, et al. 2005; Tantillo and Mathisen 1995; Wogalter and Vigilante 2003).

Therefore, the consumer brief summary should be presented visually in a manner designed for ease of use by consumers. Carrying over elements of the main body of the ad (such as logos and branded colors) may help the reader understand the connection between the consumer brief summary and the promotional piece. Font size and style should be selected or designed for readability. Using double spacing between paragraphs and indentations, as opposed to plain block paragraphs, helps maximize background space (also called *white space*) and improves readability. Arranging information in text boxes (i.e., paragraphs of information on a similar topic surrounded by borders) with headings (Hyona and Lorch 2004) and other attention-drawing symbols (e.g., bullets, capitalization of select words or phrases) may also be useful to consumers.

B. Content

FDA's current thinking is that the consumer brief summary should provide clinically significant information on the most serious and the most common risks associated with the product and omit less pertinent information. FDA recommends that firms look to available standards to determine which risks should be included. For example, FDA-approved patient labeling and Medication Guides, if available for the drug at issue, may be an appropriate starting point to determine which risks should be included in the consumer brief summary and, in fact, may contain the same risk information that should appear in the consumer brief summary. However, some information in patient labeling—such as information found in the Directions for Use section—is not necessary to include in the consumer brief summary. Additionally, information not contained in patient labeling, such as information about certain relevant drug risks, might need to be added to the consumer brief summary.

[9] "Signaling" has been defined as the use of "writing devices designed to emphasize aspects of a text's structure or content without altering the information in the text" (Lorch, Lorch, et al. 1993).

Under the final rule for Requirements on the Content and Format of Labeling for Human Prescription Drug and Biological Products (the "Physician Labeling Rule" or PLR),[10] the labeling of new and recently approved products[11] must include Highlights of Prescribing Information (Highlights). FDA believes the criteria used for selecting risk information for the Highlights section are an appropriate reference for firms to use when determining which risk information topics to address in the consumer brief summary. See 21 CFR 201.57(a). In addition, information in the consumer brief summary should be placed in an order similar to information in the Highlights section (Boxed Warning followed by Contraindications, Warnings and Precautions, etc.). However, since information in the Highlights section is intended for use in conjunction with information in the full PI and the full PI is not being provided, generally the information in the consumer brief summary should be more detailed and provide more material information than what is contained in the Highlights. Furthermore, although the PLR is not applicable to all drugs, similar information can be taken from the analogous sections of each drug's PI.

For each of the formats discussed below, or for alternative formats, information addressing the following should be included:

- Boxed Warning[12]
- All Contraindications
- Certain information regarding Warnings and Precautions:
  - the most clinically significant information from the Warnings and Precautions section(s) of the PI;
  - information that would affect a decision to prescribe or take a drug;
  - monitoring or laboratory tests that may be needed;
  - special precautions not set forth in other parts of the PI; and
  - measures that can be taken to prevent or mitigate harm.

FDA also recommends that the most frequently[13] occurring Adverse Reactions be included in the consumer brief summary.[14] If a product has more than one indication, the most common Adverse Reactions for each indication being promoted should be included, if included in the PI, rather than pooled results for all indications (which could include indications that are not being promoted). Adverse Reactions should be listed in the same order as in the PI.

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[10] Requirements on the Content and Format of Labeling for Human Prescription Drug and Biological Products (71 FR 3922, Jan 24, 2006).

[11] The PLR applies to prescription drugs that were approved after, on, or five years prior to the effective date of the rule, and to older drugs for which certain supplements are submitted (21 CFR 201.56(b)).

[12] Certain recommendations will not apply to all drugs. For example, not all drugs have a Boxed Warning. If a recommendation is not applicable, the information should be omitted.

[13] The list of Adverse Reactions identified as most frequently occurring or most common is usually generated from a table of Adverse Reactions from clinical trials in the approved labeling. Rates of most common Adverse Reactions vary, but should be appropriate to the nature of a drug's Adverse Reactions profile and the size and composition of the safety database. See the guidance for industry entitled *Labeling for Human Prescription Drug and Biological Products—Implementing the PLR Content and Format Requirements* (Feb 2013), available on the Internet at http://www.fda.gov/Drugs/default.htm under Guidances (Drugs).

[14] This recommendation comports with the information required in the Highlights section (21 CFR 201.57(a)(11)), and is also applicable to drugs to which the PLR does not apply.

Other important Adverse Reactions, such as those that are serious[15] or those that lead to discontinuation of the drug or dosage adjustment, should be included unless they are repeated elsewhere in the PI (e.g., risks included in Warnings and Precautions).

Material information regarding any of these risks may also include the severity of the risks, such as whether they are debilitating, life-threatening, irreversible, or whether stopping the medication will alleviate or mitigate the risks. If early warning signs of risks are known, consumers should be given information about these signs and the importance of informing their health care provider about the signs. Firms may also include information regarding the need for monitoring or testing during treatment. Other material information may be relevant depending on the drug and its risk profile.

FDA also believes that the consumer brief summary should include the indication for the use being promoted, any clinically significant drug interactions,[16] and information regarding topics or issues consumers should discuss with their health care providers (e.g., other drugs they are taking or pre-existing conditions). Other types of information may be included if relevant to the drug or specific indication referred to in the promotion (e.g., that a drug is not indicated for use for more than 4 weeks for the indication being advertised even if a different indication allows for a longer use). Information relating to special populations (e.g., children, the elderly, pregnant or nursing women, people with liver or renal impairment) should be included if they are of particular concern based on the drug's known or potential safety profile (e.g., not recommended for use in children based on adverse events; not for use in nursing women due to the potential for harm to the infant).

In general, certain information found in the PI or in FDA-approved patient labeling can be excluded from the consumer brief summary. This information might include dosage and administration, how the drug is supplied, clinical pharmacology, specific directions regarding use of the drug (such as how to perform an injection or how to use a patch), or how long the drug takes to work. However, excluding certain information from the consumer brief summary does not mean that the same information can be omitted from other parts of the promotional piece (e.g., information that a drug is administered via an injection versus orally might be material information that is required in the main body of the promotional piece, while detailed instructions for use may be omitted from the consumer brief summary).

FDA also recommends that, because the risk information in the consumer brief summary is not comprehensive, the consumer brief summary should include a statement (1) reminding

[15] *Serious Adverse Reaction* refers to any reaction occurring at any dose that results in any of the following outcomes: death, a life-threatening adverse experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability or incapacity, or a congenital anomaly or birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious Adverse Reactions when, based upon appropriate medical judgment, they may jeopardize the patient or subject, and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. See the guidance for industry entitled *Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products—Content and Format* (Jan 2006).

[16] For example, for a drug with PLR labeling, typically the most clinically significant drug interactions appear in the Contraindications or Warnings and Precautions sections.

consumers that the information presented is not comprehensive, (2) suggesting that consumers speak to their health care provider or pharmacist, and (3) containing a toll-free telephone number or website address (uniform resource locator or URL) where consumers can obtain the FDA-approved product labeling.[17] For example:

- *The risk information provided here is not comprehensive. To learn more, talk about [drug name] with your health care provider or pharmacist. The FDA-approved product labeling can be found at www.drugnamePI.com or 1-800-555-DRUG.*

- *This information is not comprehensive.*
- *How to get more information:*
  - *Talk to your health care provider or pharmacist*
  - *Visit www.drugnamePI.com to obtain the FDA-approved product labeling*
  - *Call 1-800-555-DRUG*

The consumer brief summary may also contain a title such as "Important Facts" or "Summary of Information about . . ." along with the drug's name.[18]

When the PI is revised, the consumer brief summary for the drug must be reviewed and revised promptly if pertinent information has been changed (21 CFR 314.70(a)(4), 601.12(a)(4)).

C. Format

Various formats may be used when conveying information in the consumer brief summary. Although other formats may be acceptable, the following two sections describe recommended formats that have been tested in research.

1. Prescription Drug Facts Box

Ever since the labeling rule for OTC human drugs was finalized more than a decade ago,[19] OTC products have contained a Drug Facts box on each product. For the consumer brief summary, a layout similar to the OTC Drug Facts box may be familiar to consumers and may offer advantages over other formats. In a study testing various brief summary formats, the Drug Facts box format resulted in better recall of the risk information when compared to the traditional format (which was written in consumer-friendly language). Consumers in the same study who saw the Drug Facts box also reported that they felt more confident in their ability to use the information when compared to consumers who saw the traditional format. In addition, consumers had more positive attitudes toward the Drug Facts box format than toward two other

[17] This recommendation is distinct and separate from the "adequate provision" requirement for broadcast advertisements found at 21 CFR 202.1(e)(1). This guidance only covers print advertisements and print promotional labeling and does not apply to broadcast advertisements.

[18] See the revised draft guidance for industry entitled *Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling* (Nov 2013). When final, this guidance will represent the FDA's current thinking on this topic.

[19] See Food and Drug Administration, Final Rule; Over-The-Counter Human Drugs, Labeling Requirements (64 FR 13254, Mar 17, 1999).

formats: the traditional format and a format that is structured like the Highlights section of the PI (Aikin, O'Donoghue, et al. 2011).

Under a prescription Drug Facts box format, information could appear within a box similar to the OTC Drug Facts box. Standardized headings may assist consumers in locating and comprehending important drug information. For example:

- Uses
- Do not use if you
- Warnings
- Ask a health care provider before use if
- When using this product you may have

The recommended content for this format is set forth in section III.B above, and the recommendation to use consumer-friendly language also applies.

2. Question and Answer

A Question and Answer (Q&A) format simulates a dialogue using personal pronouns, thus increasing consumer interest in, and comprehension of, the information. The study testing brief summary formats found that consumers had more positive attitudes toward a Q&A format than the traditional brief summary (which was written in consumer-friendly language). However, this study did not find a difference in risk recall or confidence between the Q&A format and the traditional format. Because consumers preferred the Q&A format and the format did not decrease risk recall (Aikin, O'Donoghue, et al. 2011), this format is recommended over the traditional brief summary.

Under the Q&A format, information in the consumer brief summary could appear in columns or a similar layout. Headings would be framed in the form of questions, for example:

- What is [drug] used for?
- When should I not take [drug]?
- What Warnings should I know about [drug]?
- What should I tell my health care provider?
- What are the side effects of [drug]?
- What other medications might interact with [drug]?

The recommended content for this format is set forth in section III.B above, and the recommendation to use consumer-friendly language also applies.

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