



University of California  
San Francisco

School of Pharmacy  
Center for Consumer Self Care

May 10, 2004

R. William Soller, Ph D  
Executive Director  
Center for Consumer Self Care

3333 California Street, Suite 420  
San Francisco, CA 94143-0613  
tel 415/502-7633  
fax 415/502-0792  
email soller@itsa.ucsf.edu

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm 1061  
Rockville, MD 20852

RE: Docket No. 2004D-0042: Draft Guidances for Industry on Improving Information About Medical Products and Health Conditions; Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements - Draft Guidance

[Federal Register: February 10, 2004 (Volume 69, Number 27)]

To Whom It May Concern:

FDA's draft guidance on disclosing risk information in consumer-directed print advertisements through the Brief Summary has recently come to the attention of the UCSF Center for Consumer Self Care, and we take this opportunity to offer comments on this document, noting that FDA has explicitly solicited views of interested parties on this matter.

The UCSF Center for Consumer Self Care (hereafter, "the Center") is a component of the University of California, San Francisco School of Pharmacy and aligns its program activities in research, policy, education, and community service with its mission to help people take a central role in their own health care. Clear, concise, consistent health communication is vital to consumer-centered self-care, and hence the subject of the draft guidance is of high importance. The UCSF Drug Information Analysis Service is a component of the Center for Consumer Self Care. The Center

2004D-0042

C24

submits these comments independent from any other groups or organizations. With the opportunity to provide public comment on the Brief Summary, the Center raises herein a number of very specific questions concerning the consistency of FDA's public health policy relating to health communication approaches to FDA-regulated pharmaceutical products. Specifically, the Center's concerns focus on the disparity in health communication approaches to Rx- and OTC-drug information oriented to consumers. The overarching question is:

*Should FDA take different approaches to the consumer-directed labeling of Rx and OTC drug products, when the target populations for both categories of medicines are the same - i.e., the consumer?*

The answer to this question is straightforward. It is no, and the reasons are amplified in these comments. FDA should take the same approach to consumer-directed labeling of Rx and OTC drug products.

Our comments are organized as follows:

- A. Recommendations
- B. Rationale for Recommendations
- C. Specific Findings
- D. Conclusion

### **A. Recommendations**

To bring consistency to FDA's policies pertaining to the consumer-directed labeling of Rx and OTC drug products, the Center specifically requests the following:

- 1. FDA should address all the questions and issues raised in these comments as a means to create consistency in its consumer labeling policy for all medicines.**

**2. Formatting and sequencing information in all FDA-regulated written drug information oriented to consumers should be founded on sound principles of readability and modeled after the OTC “Drug Facts” label, including incorporation of the following list of specific suggestions that are explained in the Major Section entitled Specific Findings:**

- (1) The Brief Summary should be tailored to contain the most serious and the most common risks of a product.
- (2) A single format for the Brief Summary should be adopted, and it should be modeled after the OTC “Drug Facts” label.
- (3) FDA-approved patient labeling as defined in the Draft Guidance Is just a portion of the essential information needed in the Brief Summary.
- (4) The format of the emerging second-generation of Brief Summaries (e.g., Exhibits C-E) do not go far enough in creating the optimal drug information targeted to consumers.
- (5) Minimum type sizes should be established for the Brief Summary, similar to the OTC “Drug Facts” label, including a 6-point minimum type size for information text.
- (6) Headings and subheadings in the Brief Summary should be constructed the same as those in the OTC “Drug Facts” label, to the extent possible.
- (7) Unnecessary repetition of information should be avoided, if possible.
- (8) Technically dense information should be avoided in the Brief Summary.
- (9) The sequence of information in the Brief Summary should be the same as that sequence required for the OTC “Drug Facts” label.
- (10) Bulleted lists should be used where possible.
- (11) Use of “All Caps” should be avoided.

- (12) A poison control warning should be required in the Brief Summary; the pregnancy warning should appear in the same section of the Brief Summary.
- (13) “Drug Facts” with “Highlights” and “Rx Only” should be the leading terms at the top of the Brief Summary (Exhibit F), and placement of the notice concerning availability of complete product information and the notice of toll free number availability should appear at the top of the Brief Summary.
- (14) Simplification of terms is essential for clear health communications.

**3. A single type of format should be adopted for the Brief Summary.**

While FDA proposes an implied transitional approach that would allow companies to choose one of three formats, including the status quo, it is likely that some companies will delay implementation of the preferred, more consumer-friendly formats. However, if a single format is not chosen, FDA should permit use of a “Drug Facts” format for Brief Summaries, and establish a tracking mechanism to assess industry-wide progress on the adoption of consumer-friendly Brief Summaries, as defined in the context of the issues raised in these comments. In the event that industry does not voluntarily adopt the use of consumer-friendly Brief Summaries, then FDA should re-visit this issue through regulation that would specify a date certain when all Brief Summaries would be in a specified consumer-friendly format.

**4. FDA should consider a requirement that Brief Summaries are tested prior to use in advertising using a protocol similar in design to the established OTC label comprehension study protocol.**

FDA should evaluate and decide with cogent rationale why OTC “Drug Facts” labeling for Rx-to-OTC switch products must be tested via label comprehension studies, while such testing is not required for DTC Brief

Summaries, when both types of health communication are expected to be used at the time the consumer takes the product (i.e., the OTC label is available on the product at time of each use, and the Brief Summary so states in the introductory paragraph, see Exhibits A<sup>1</sup>, C<sup>2</sup>, and D<sup>3</sup>).

## B. Rationale for Recommendations

1. Clear, credible and consistent health communication to consumers through specific information about a drug's active ingredients, use/s, warnings and directions is vital to safe and effective use of medicines.
2. When conveying information to the average person about a potentially complex process involving detailed concepts relating to “what,” “when,” “where,” “how,” “how much/little,” and “why” it is both logical and good teaching practice to use a consistent approach. Such consistency is more likely to achieve learning objectives, and allow reinforcement of information from one episode of information exchange to another. Where there are artificial or unsubstantiated distinctions in classes of users of information in the context of a common communication objective, those distinctions should be dispelled in favor of consistency for the communication objective. This conceptual approach should be realized for health communications to consumers about Rx and OTC drugs.

---

<sup>1</sup> Rx consumer advertisement and Rx Brief Summary for Nexium® in *Time Magazine*, April 26, 2004.

<sup>2</sup> Rx consumer advertisement and Rx Brief Summary for Levitra® in *Kiplinger's Personal Finance*, May 2004.

<sup>3</sup> Rx consumer advertisement and Rx Brief Summary for Wellbutrin XL® in *U.S. News & World Report*, April 26, 2004.

3. Prescription (Rx) drugs and nonprescription (OTC, over-the-counter) drugs contain the same categories of essential information needed for the safe and effective use of the product by the patient or consumer.

Categories of common information needed for all drug products include: active ingredients; purpose of indication; uses; warnings, including special warnings specific to the active ingredient or use of the product, absolute contraindications (i.e., “do not use”), relative contraindications (i.e., “ask a doctor before use if \_\_\_\_”), in-use precautions (e.g., stop use and see a doctor if ...”), use or contraindication for use in pregnancy and breast-feeding, the need to keep the medication out of the reach of children, and possible other information specific to the product (e.g., storage conditions, etc.).

4. Rx information that is directed to consumers and the OTC “Drug Facts” label are both used by consumers as part of the consumer’s selection process for drug products.

Prescription drug advertising to consumers, also called “direct-to-consumer (DTC) advertising,” is part of the process of selection of drug products by consumers. Indeed, DTC is well known as a source of information that leads consumers to request specific prescription drugs from their physicians.<sup>4</sup> From the September 22-23, 2003 public meeting on DTC, FDA reports that, “DTC seems to inform patients about available treatments and foster discussions between patients and physicians ... [and] ... [P]atients who ask about a specific drug are likely to be prescribed that drug.” While the physician may have the final say in terms of whether a prescription is

---

<sup>4</sup> Braman, A., and K. Aiken: Research on DTC ads presented at public meeting: Influence of ads, ways to improve brief summary aired. *News Along the Pike*, December 3, 2003. <http://www.fda.gov/cder/pike/nov2003.htm#DTC>

written for a product that the consumer has requested from his or her physician, this is immaterial in this context, since under the FDC Act essential Rx drug information should be given to the individual, if the product is to be advertised to consumers.

The OTC drug label (21CFR201) and its advertising is also a part of the process of selection of drug products by consumers. Indeed, the creation of the “Drug Facts” label for OTC drug products included discussion of how the “Drug Facts” format would allow product comparisons at the retail level. As a result, FDA acknowledged in the OTC “Drug Facts” Final Rule that:

“...a standardized appearance and standardized content, including various ‘user-friendly’ visual cues, would help consumers locate and read important health and safety information and allow quick and effective product comparisons, thereby helping consumers to select the most appropriate product.”<sup>5</sup> (emphasis added)

In sum, selection of drug products is not only a health professional function, it is in today’s regulatory environment both a consumer function and a health professional function. A standardized OTC drug label format to aid the selection process for consumers has been acknowledged by FDA. The Rx drug information component of the consumer drug selection process should be constructed in a way that is very similar, if not identical, to that of the OTC drug label.

5. Both the OTC “Drug Facts” label and the Brief Summary are intended for use after product selection each time a product is taken by the consumer.

The OTC “Drug Facts” label appears on the retail product at the time of selection for first, as well as repeated, use. The common first paragraph of

---

<sup>5</sup> Food and Drug Administration. Over-The-Counter Human Drugs; Labeling Requirements; Final Rule. Federal Register: March 17, 1999;(64):13253-13303.

the Rx Brief Summaries found in recent magazines advises the consumer to read the information in the Brief Summary each time the consumer gets a refill (see Exhibits A<sup>6</sup>, B<sup>7</sup>, C<sup>8</sup>, D<sup>9</sup>, E<sup>10</sup>). As such, the intent and the timing of the communication of drug information to consumers are the same for Rx Brief Summary and the OTC drug product label. The intent is that the product user (i.e., patient and consumer) should self-access essential information about safe and effective drug product just before self-dosing, as well as at the time of self-selection as noted above.

6. A consumer will have the same visual acuity limitations irrespective of whether s/he is taking a Rx or an OTC drug product. The OTC “Drug Facts” label has a minimum required type size,<sup>11</sup> yet Rx DTC Brief Summaries have no similar minimum standard, some being as small as 4.5 point type (see Exhibit B<sup>12</sup>).

Visual acuity problems in the elderly can potentially contribute to safety problems with drugs. If the visual acuity problems are sufficient in relation to the nature of the consumer-directed drug labeling, the labeling may be so difficult to read as to lead seniors to forego reading the drug information.

Visual acuity declines with age.<sup>13</sup> More than two-thirds of visually-impaired

---

<sup>6</sup> Rx consumer advertisement and Rx Brief Summary for Nexium<sup>®</sup> in *Time Magazine*, April 26, 2004.

<sup>7</sup> Rx consumer advertisement and Rx Brief Summary for Allegra<sup>®</sup> in *Newsweek*, April 26, 2004.

<sup>8</sup> Rx consumer advertisement and Rx Brief Summary for Levitra<sup>®</sup> in *Kiplinger's Personal Finance*, May 2004.

<sup>9</sup> Rx consumer advertisement and Rx Brief Summary for Wellbutrin XL<sup>®</sup> in *U.S. News & World Report*, April 26, 2004.

<sup>10</sup> Rx consumer advertisement and Rx Brief Summary for Strattera<sup>®</sup> in *U.S. News & World Report*, April 26, 2004

<sup>11</sup> Food and Drug Administration. Over-The-Counter Human Drugs; Labeling Requirements; Final Rule. Federal Register: March 17, 1999;(64):13253-13303.

<sup>12</sup> Rx consumer advertisement and Rx Brief Summary for Allegra<sup>®</sup> in *Newsweek*, April 26, 2004.

<sup>13</sup> Healthy People 2010 Vision, <http://www.healthyvision2010.org/populations/index.asp>

adults are over age 65 years, the group with the highest number of chronic diseases and concomitant drug usage. More women are visually impaired than men are because, on average, women live longer than men do. By 2030, the number of people over 65 is estimated to be over 70 million. As the population ages, therefore, the number of people with visual impairment and other aging-related disabilities can be expected to increase.

To address visual acuity problems of the elderly and others, FDA created a 6-point type size requirement for information text on OTC drug labels. With the continuing push for the conversion of prescription drugs to OTC status, many of the consumer-advertised Rx products that the elderly might have used on prescription will be available OTC with the consumer-friendly OTC “Drug Facts” format, using the required minimum 6-point type size. If a minimum 6 point type is important for the elderly consumer using OTC drugs, then why would it not also be important for the elderly consumer/patient using the same drug on prescription when it was advertised to consumers with an accompanying Brief Summary? There is simply no evidence-based reason why the OTC “Drug Facts” label and the Brief Summary should not have the same minimum type size requirements for text.

Acting now to address the visual acuity issues of the elderly in the context of health communication via drug labeling is important for today’s seniors, and even more so given the population trends. Indeed, FDA recognizes the importance of drug safety in the elderly. For example, FDA states in its web site under “Medications and Older People”<sup>14</sup>:

---

<sup>14</sup> Food and Drug Administration: [http://www.fda.gov/fdac/features/1997/697\\_old.html](http://www.fda.gov/fdac/features/1997/697_old.html), accessed April 22, 2004.

“People age 65 and older consume more prescription and over-the-counter (OTC) medicines than any other age group, according to the National Institute on Aging. Older people tend to have more long-term, chronic illnesses--such as arthritis, diabetes, high blood pressure and heart disease--than do younger people. Because they may have a number of diseases or disabilities at the same time, it is common for older people to take many different drugs. The Food and Drug Administration is working to make drugs safer for older people, who consume a large share of the nation's medications. People over age 65 buy 30 percent of all prescription drugs and 40 percent of all over-the-counter drugs.” (emphasis added)

7. FDA should take advantage of the considerable public comment and work that went into creating the OTC “Drug Facts” label. Indeed, the advantages of the OTC label format have already been acknowledged by the agency.

The new format for the OTC label, called “Drug Facts,” was developed based on generally accepted principles of readability and with FDA-sponsored research and numerous comments from experts in academia and industry over a period of over 5 years.<sup>15</sup> It is widely regarded as a vast improvement over the original OTC label content and format, which often resembled long, daunting, dense single-line paragraphs of required drug information, with no accountability to readability principles. Examples of this type of “original OTC label and content format” for a current Rx Brief Summary are shown in Exhibits A<sup>16</sup> and B<sup>17</sup>.

Indeed, FDA stated in the Final Rule for the OTC “Drug Facts” label:

---

<sup>15</sup> Food and Drug Administration. Over-The-Counter Human Drugs; Labeling Requirements; Final Rule. Federal Register: March 17, 1999;(64):13253-13303.and based on personal involvement of R. W. Soller in the development of the OTC industry’s voluntary Label Readability Guidelines and of the OTC “Drug Facts” with FDA health professionals, during Soller’s term at the Consumer Healthcare Products Association.

<sup>16</sup> Rx consumer advertisement and Rx Brief Summary for Nexium® in *Time Magazine*, April 26, 2004.

<sup>17</sup> Rx consumer advertisement and Rx Brief Summary for Allegra® in *Newsweek*, April 26, 2004.

“The agency stated that a standardized labeling format would significantly improve readability by familiarizing consumers with the types of information in OTC drug product labeling and the location of that information. In addition, a standardized appearance and standardized content, including various “user-friendly” visual cues, would help consumers locate and read important health and safety information and allow quick and effective product comparisons, thereby helping consumers to select the most appropriate product.”<sup>18</sup>

8. Improving all Brief Summaries to bring them up to par with OTC consumer labeling (i.e., using label readability principles, such as more white space, bulleted lists, outline format) and requiring larger type sizes might be viewed as potentially creating longer Brief Summaries, thereby leading to more pages of advertising and higher cost to industry. Irrespective of the cost, it could be also viewed as a disadvantage to consumers if Rx drug information through DTC advertising were not available to them.

However, FDA’s new approach to require only the most important information for Rx drug product use will potentially decrease the total amount of information on the page, so that in most cases any increases in label length due to use of readability principles would be offset. Such formatting and type size changes would also be consistent with the OTC drug approach, and would likely create a more consumer-friendly label, yielding important overall public health advantages, as stated above.

To exemplify this point, see the detailed comments below for an example of a current DTC label that we have formatted in the OTC “Drug Facts” label format. The original Brief Summary, from which the revised OTC “Drug Facts” brief summary was created, and the revised Brief Summary in

---

<sup>18</sup> Food and Drug Administration. Over-The-Counter Human Drugs; Labeling Requirements; Final Rule. Federal Register: March 17, 1999;(64):13253.

the OTC “Drug Facts” format are the same length. Therefore, it is likely that there would be little economic impact if an OTC “Drug Facts” format for the Brief Summary were to be required; indeed, it may actually decrease the total advertising space.

9. FDA has used the “Drug Facts” format for other consumer product areas, including “Nutrition Facts” and “Dietary Supplement Facts.” Hence, there is precedence in the consumer arena for such a “Facts” format.

The fact that foods have two differently named formats derives in part from defined legal requirements as well as from commonly held views about the essentiality of nutrients found in conventional foods vs. the role of supplements.

For drug products which are evaluated under the same conceptual framework of benefit and risk and which are used in the context of the same principles of safety and effectiveness, there is no basis for creating a vastly different format for Rx labeling for the consumer (i.e., the Brief Summary) than for OTC drug labels. It may be that a different heading, such as “Drug Facts....Rx only”, or some such phrase would be useful to help the consumer understand differences in availability (i.e., via the professional channels of drug distribution vs. retail distribution; see heading in Exhibit F).

10. Finally, a public health need for different Rx and OTC labeling for consumers has not been credibly shown. There is no credible research-base for establishing different formatting and content approaches to consumer labeling for Rx and OTC medicines. A vague and unsubstantiated claim that the consumer should view an OTC medicine differently than a patient

should view an Rx medicine is a specious argument. An OTC medicine should be taken as seriously as a Rx medicine.

In summary, the distinction between Rx and OTC drugs is a legal and regulatory distinction predicated on the need for supervision and dispensing by a licensed practitioner. Essentially, this legal/regulatory distinction prevents open consumer access to drug ingredients that might otherwise be dangerous if taken without a professional diagnosis, with or without needed laboratory information. However, as a practical matter in terms of today's permitted framework, consumer self-selection of Rx drugs through consumer-directed advertising and of OTC drugs via retail self-selection is encouraged. Any distinction between Rx and OTC for purposes of the presentation of Rx drug information in consumer advertising as currently exists simply cannot be regarded as authentic.

Hence, a common policy framework should be developed that harmonizes the format and content of FDA-regulated consumer-directed health communications, irrespective of whether the drug product is Rx or OTC.

### **C. Specific Findings**

There is insufficient foundation to support the apparent current discrepancy in approaches to the OTC "Drug Facts" label and the Rx Brief Summary - both intended as health communication tools during product selection and product use, as noted above in Section B.

A review of current DTC advertising by the Center is the basis for the specific findings elaborated below. The Center asks FDA to address each of these

points as it develops a final guidance and, if need be, regulations relating to the Brief Summary.

**1. The Brief Summary Should Be Tailored to Contain the Most Serious and the Most Common Risks of a Product.**

FDA states in the Federal Register announcement seeking comments on the Draft Guidance that “a print advertisement that discloses the most serious and the most common risks of a product is a better way of communicating risk information to patients than the current lengthy and technical brief summary.”<sup>19</sup>

The Center supports this approach. However, FDA should not ride the pendulum of consumer-friendliness to the other extreme, where the information in the revised Brief Summary (i.e., Highlights) is so contracted as to be a coarse sketch of potential toxicity and use information, and thereby even unhelpful. Rather, a balance should be sought, as is done on the OTC label, that defines the essential information on Rx safety *and* effectiveness information (see also below) needed for self-selection and safe use. For example, the OTC label does not include all information about possible side effects from the active ingredient, but does give essential risk and benefit information for informed decision making through a consumer-centered approach.

**2. A Single Format for the Brief Summary Should Be Adopted, and It Should Be Modeled After the OTC “Drug Facts” Label.**

In the guidance, FDA proposes that companies may use any one of three formats for the Brief Summary: “(1) present all risk information from the FDA-approved professional labeling; (2) reproduce FDA-approved patient

---

<sup>19</sup> Food and Drug Administration. Federal Register: February 10, 2004;69:6308-9.

labeling, either in its entirety or as modified to omit less important risk information; (3) provide the risk information that would be appropriate for-FDA-approved Highlights.”<sup>20</sup> If a company uses one of these three options, then FDA states that it “does not intend to object to a consumer-directed print advertisement for a prescription drug on the ground that it does not present risk information in compliance with the brief summary requirement.”

In considering these options and other related information in the Draft Guidance, the Center has the following comments.

First, in the Draft Guidance FDA negatively critiques the current approach to the “Brief Summary Requirement,” wherein each specific side effect and contraindication” is presented:

“Although this approach complies with the brief summary requirement, FDA believes it is less than optimal for consumer-directed print advertisements because many consumers do not have the technical background to understand this information.”<sup>21</sup>

If FDA therefore believes that option #1 (i.e., all risk information from professional approved labeling) is less than optimal for consumers, why is the agency proposing it as an optional solution? Permission to continue with the status quo (i.e., see Exhibits A and B) is not the way forward to more consumer-friendly Rx labeling. The Center encourages a regulatory solution that moves to a requirement for a single format for the Brief Summary, preferably one modeled after the “OTC Drug Facts” format.

---

<sup>20</sup> Food and Drug Administration. Guidance for Industry, Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements, January 2004.

<sup>21</sup> Food and Drug Administration. Guidance for Industry, Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements, January 2004.

Indeed, FDA did not opt for multiple basic formats for the OTC “Drug Facts” label, even though FDA permits some leeway, for example, as in the splitting of information on more than one panel. Rather, FDA maintained that a single format framework would be essential. Specifically, the agency contended in the Final Rule for the OTC “Drug Facts” label that the use of a single format framework will likely help consumers more easily access information as they become accustomed to how information is organized and presented.<sup>22</sup>

In sum, the Center recommends a *consumer-centered focus* to addressing the format of the Brief Summary, as was done for the OTC “Drug Facts” Final Rule. The net result will be acknowledgement that something akin to the model in Exhibit F is the preferred approach.

**3. FDA-approved Patient Labeling as Defined in the Draft Guidance Is Just a Portion of the Essential Information Needed in the Brief Summary.**

Under the Federal Food, Drug, and Cosmetic Act (the Act), FDA is responsible for regulating the advertising of prescription drugs. As stated by FDA in the Draft Guidance:

“Under Section 502(n) of the Act (21 U.S.C. 352(n)), an advertisement for a prescription drug must contain, in addition to the product’s established name and quantitative composition, a ‘true statement’ including “information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations.” (Emphasis added)

Consistent with the regulations implementing 502(n), FDA identifies the following information as needed in FDA-approved patient labeling: all

---

<sup>22</sup> Food and Drug Administration. Over-The-Counter Human Drugs; Labeling Requirements; Final Rule. Federal Register: March 17, 1999;(64):13253-13303. See also points # 4 and 6 under Rationale for Recommendations.

contraindications, all warnings, precautions, adverse reactions (“the 3-5 more common non-serious adverse reactions most likely to affect the patient’s quality of life or compliance with drug therapy”). What is missing is a stated requirement for effectiveness, per the agency’s interpretation of 502(n) (see excerpted quotation immediately above).

If the purpose of the DTC Brief Summary is to facilitate health communication of drug information to consumers to help *in self-selection* as well as *in use* (i.e., because at the top of the Brief Summary it states that it is to be read before taking the drug and at each refill), then it only stands to reason that both effectiveness information and safety information should be in the Brief Summary, as it is in the OTC “Drug Facts” Label. Hence, FDA should expand the list of required information in the Brief Summary to include all the elements found in the OTC “Drug Facts” label, at a minimum.

After all, knowledge of effectiveness aspects of labeling (e.g., directions of use) represent essential safety information in terms of ensuring the product is taken as directed. If a consumer/patient does not take the product as recommended, potential safety problems may ensue. Additionally, aspects of product administration may be unacceptable to some consumers (e.g., use of a suppository, appearance of undissolved time release capsules in stool, short dosing regimens vs. timed release formulations etc.). Thus, if the Brief Summary is also intended as a potential product selection tool, this additional information is important as well.

A persuasive support to require effectiveness and safety information in the Brief Summary stems from FDA’s observations of the presentations at the

September 22-23, 2003 public meeting on DTC and the Brief Summary. FDA concluded, based on survey data provided at the meeting that:<sup>23</sup>

“Patients do not comprehend the risks and benefits in DTC advertisements equally well.”

“One theme that arose repeatedly was the ineffectiveness of the brief summary in DTC print advertising in informing consumers about the indications, contraindications and risks of prescription medications.” (emphasis added)

Hence, there is support from the recent public hearing to expand the information in the Brief Summary to include both effectiveness and safety data, to allow the consumer to be better informed about benefits and risks.

**4. The Format of the Emerging Second-Generation of Brief Summaries (e.g., Exhibits C-E) Do Not Go Far Enough in Creating the Optimal Drug Information Targeted to Consumers.**

The first generation, or original formats, of Brief Summaries shown in Exhibits A and B (i.e., the long paragraph approach) are very difficult to navigate and are tiring to read. The emerging second generation, or newer somewhat more consumer-friendly, Brief Summaries shown in Exhibits C-E (i.e., in which the “chunking” approach to readability is used<sup>24</sup>) are vast improvements over the first generation Brief Summaries. However, much more could be done to improve the ease of information acquisition of the second-generation Brief Summaries.

---

<sup>23</sup> Braman, A., and K. Aiken: Research on DTC ads presented at public meeting: Influence of ads, ways to improve brief summary aired. *News Along the Pike*, December 3, 2003. <http://www.fda.gov/cder/pike/nov2003.htm#DTC>

<sup>24</sup> Doak, CC, LG Doak and SH Root. *Teaching Patients With Low Literacy Skills*. 2d ed. Philadelphia: Lippincott Co., 1996.

Specifically, Exhibit F shows a reformatted Brief Summary for a currently advertised Rx product, using “BRANDNAMEMED”, “INGREDIENTNAME”, and other approaches to avoid disclosure of the actual product and company. This “Drug Facts” approach should be used to create a third generation of the Brief Summary.

The “Drug Facts” approach to the Brief Summary as shown in Exhibit F:

- Is in use on OTC drug labels;
- Is considered consumer-friendly;<sup>25</sup>
- Provides both effectiveness and safety information;
- Has required minimum type sizes for headings (8 point), subheadings (6 point), text (6 point), bullets (5 point solid square) and lines (2.5 point box, 2.5 point bar line and 0.5 point hair-line) and other format requirements (e.g. right justify Purpose, all information set off by color contrast; 2 em spacing between bullets, 6.5 leading, right-justified information text);
- Uses a standard font (Helvetica Bold and Helvetica Regular);
- “Chunks” information in a logical sequence of information acquisition for drug information - Active, Purpose, Warnings [within warnings: Special Warnings, Absolute Contraindications (i.e., do not use), Relative Contraindications (i.e., ask a doctor before use), In-use Precautions; pregnancy warning, poison control warning], Directions, Other Information, Manufacturer’s name and address;
- Uses visual cues to help chunk information (e.g., lines and hair-lines between headings and subheadings, respectively), determined by FDA as useful in drug information acquisition;<sup>26</sup>

---

<sup>25</sup> Food and Drug Administration. Over-The-Counter Human Drugs; Labeling Requirements; Final Rule. Federal Register: March 17, 1999;(64):13253-13303.

<sup>26</sup> Ibid.

- Takes up the same amount of space as the currently advertised second generation Brief Summary from which this prototype was derived;
- Has a special heading to distinguish it from OTC “Drug Facts.”

If FDA decides to use a transition period to implement the guidance, then at a minimum the “Drug Facts” format should be allowed as one of the accepted approaches. FDA should then track adoption of “Drug Facts” format for the Brief Summary and, if needed, issue a future regulation requiring use of the “Drug Facts” type of format for the Brief Summary.

**5. Minimum Types Sizes Should Be Established for the Brief Summary, Similar to the OTC “Drug Facts” Label.**

The type sizes of first and second generation DTC Brief Summaries vary from 4.5 point (Exhibit B; original single paragraph format) to 8.5 point (Exhibit E; newer somewhat more consumer-friendly format). The OTC “Drug Facts” regulation specifies that the type size of OTC label text information must be 6 points or greater, with other type size specifications (see point #2 in this Section above).

Either FDA should explain why the consumer labeling (i.e., text information) for Rx drug products advertised through DTC with Brief Summaries in less than 6 point type size is adequate when it is not for OTC labeling, or the agency should consider revising the type size requirement for OTC “Drug Facts.” The Center does not favor the latter proposition, and it is unlikely the agency has an adequate explanation for the former. Hence, the agency should adopt the same type-size requirements for both OTC “Drug Facts” labeling and for DTC Brief Summaries - i.e.,  $\geq$  6 point type size, depending on the text or format element.

Although it might be conjectured that a minimum 6 point type size would increase the size of the Brief Summary leading to greater expense in purchasing advertising space, this is not necessarily so. With FDA prioritizing the information needing to be in the warning, a third generation more consumer-friendly “Drug Facts” Brief Summary will likely *not* be longer, but will be shorter in length, thereby being either cost-neutral or perhaps even yielding a financial incentive to companies due to less cost for advertising space.

**6. Headings and Subheadings in the Brief Summary Should Be Constructed the Same as Those in the OTC “Drug Facts” Label, to the Extent Possible.**

The nature of the headings and subheadings in the second generation Brief Summary (e.g., Exhibits C, D, E) appear to be an attempt to make the information seem engaging to the reader. The OTC “Drug Facts” label uses briefer and more succinct headings and subheadings (e.g., re subheadings: “Who should not take Strattera?” in the Brief Summary of Exhibit E *vs.* “Do not take...” in the OTC “Drug Facts” label format of the Brief Summary of Exhibit F). We are unaware of any information that specifically and credibly addresses whether the conversational sentence in a heading or subheading conveys information better than a briefer more succinct heading or subheading.

We recommend use of the more succinct OTC “Drug Facts” approach to headings and subheadings, simply because fewer words convey information more easily, more directly, and more quickly.

In this regard, the agency should consider the way in which consumers access information. “Warm and fuzzy” language in a conversational

question format may be less important than more direct language that (a) emphasizes in tonality the importance of a contraindication and (b) is briefer yielding greater white space, which itself is accepted as an important component of consumer friendly information.<sup>27</sup>

Finally, the shorter/briefer format for headings and subheadings of the “Drug Facts” label is in current use for consumer OTC drug products, supporting the OTC approach as the preferred approach to bringing consistency to consumer use of drug information. Consumers will soon become accustomed to the OTC “Drug Facts” format, if they are not already, so that any argument that the question format for subheadings makes the Rx information less imposing seems hollow. Indeed, one would want Rx drug information to consumers to be at least “as imposing” in tonality as OTC drug information to consumers.

In sum, FDA should explain cogently why the use of questions as headers in the Rx Brief Summary, and not simple headers (Active Ingredient, Use, Warnings, Directions, Other Information) as is used in the OTC “Drug Facts” label, is a preferred means of communicating with consumers about drug information? The Center favors the OTC “Drug Facts” headers and subheadings, as they are simple, direct, and help to develop “white space” in the labeling information, which itself is important to creating consumer-friendly information. If FDA finds the question format is preferred, then FDA should consider revisiting how headers and subheadings are constructed on OTC labels, as a means to harmonize its consumer drug labeling policy.

---

<sup>27</sup> Doak, CC, LG Doak and SH Root. *Teaching Patients With Low Literacy Skills*. 2d ed. Philadelphia: Lippincott Co., 1996.

## **7. Unnecessary Repetition of Information Should Be Avoided, If Possible.**

Where possible, repetition of information in the Brief Summary should be avoided. This sentence is a perfect example why (i.e., compare previous sentence with the heading of point #7 above).

Specific to the Brief Summary, it is not necessary to state as a heading, “WHAT SHOULD YOU DISCUSS WITH YOUR DOCTOR BEFORE TAKING LEVITRA?” followed by “Before taking LEVITRA, tell your doctor about all your medical problems, including if you: ...” (Exhibit C). This is redundant and unnecessary, and the second statement would suffice, saving space and speeding information acquisition by the consumer.

However in some cases, there may be a rationale for repeating certain information in different areas of the OTC label or Brief Summary. For example, in the Model Brief Summary in OTC “Drug Facts” format (Exhibit F), the “Seizure Warning” is placed under “Special Warnings.” Under “Directions” relating to what a user might do if a dose is forgotten, the “chance of seizures” is repeated.<sup>28</sup> Here, the chance of seizures is stated to provide the explanation for why the specific direction is important. Giving relevance to very important information on the label may therefore justify a certain degree of repetition in some cases.

## **8. Technically Dense Information Should Be Avoided in the Brief Summary.**

The second generation Brief Summaries presented in this submission as Exhibits C-E do not contain technically dense information (e.g., data tables)

---

<sup>28</sup> Specifically, the model Brief Summary provides a detailed “Seizure Warning” and also states under Directions: “If you miss a dose, do not take an extra tablet to make up for the dose you forgot. Wait and take your next tablet at the regular time. This is very important. Too much BRANDNAMEMED can increase your chance of seizure.”

as the first generation Brief summaries do (see Exhibits A and B). This approach is supported by the Center and should be continued.

**9. The Sequence of Information in the Brief Summary Should Be the Same as That Sequence Required for the OTC “Drug Facts” Label.**

There are many differences in the sequence of information found in the Brief Summaries for Rx drugs vs. that of the OTC “Drug Facts” label. The core question is, why should there be such differences? What evidence is there that the Brief Summary sequence is better or even as good as that in the OTC “Drug Facts” label? The information sequence for the “Drug Facts” label was carefully evaluated and debated publicly during the development of the “Drug Facts” regulation. It was generally felt that it was important to:

- Place the active ingredient and purpose/uses first, as these are important in initial selection of the product re: (a) framing the entire health communication episode with a description of use; and (b) giving information (active ingredient) to help a selection decision re: potential dual dosing of products with the same ingredient, potential drug interactions with products the consumer might already be taking and allergy to the active ingredient;
- Place Warnings second, giving (a) specialty warnings (i.e., those of highest concern) first placement, followed by absolute contraindications (do not use), relative contraindications (do not use unless you have talked to your doctor or pharmacist), in-use precautions (e.g., stop use and ask a doctor if ...), and then general warnings (i.e., pregnancy warning and registry information, if any, and the poison control warning, “keep out of the reach of children”).

The newer second generation Brief Summaries contain a section that specifies what a consumer should discuss with her/his doctor before starting Rx drug therapy (see Exhibit C, left column, “What should you discuss with your doctor before taking LEVITRA?”). This is equivalent to the OTC “Drug Facts” Warning section, “Ask a doctor before use if...” The same Brief Summary (Exhibit C) also contains Warning information about in-use precautions (e.g., right column of Exhibit C Brief Summary, “How should you take LEVITRA?”). These two components of the *Warning* information for LEVITRA are separated by a considerable amount of *Directions* information relating to how to take the product. Sound label construction practice would suggest all warning information should be kept together and in a logical sequence, if possible. [Note, Exhibits D and E present the same interruption of Warning information in the Brief Summary.]

The Center favors the consolidation of Warning information prior to directions of use, and believes that this should be consistent for Rx drug consumer labeling and OTC drug consumer labeling.

#### **10. Bulleted Lists Should Be Used Where Possible.**

Where possible, the Brief Summary should use a bulleted format for information that may appear in list format. For example, in Exhibit C the section for “HOW SHOULD YOU TAKE LEVITRA?” could be better formatted with a bulleted list, as shown for a “Drug Facts” format (Exhibit F). This would be true for listing side effects, etc.

## **11. Use of All Caps Should Be Avoided.**

As explained in detail during the development of the “Drug Facts” label, the use of All Capital letters (All Caps) should be avoided. Because there are no ascenders and descenders in the lettering<sup>29</sup> when All Caps are used, text is more difficult to read easily. FDA’s Division of OTC Drug Products accepted this view in developing the “Drug Facts” labeling and specified in the final rule that All Caps would not be used to highlight headers or other items of importance.<sup>30</sup>

While we are aware that there are other recent DTC Brief Summaries that use All Caps in information text, Exhibit C has examples of All Caps in headings. With the exception of the brand name, use of All Caps should be discouraged in all drug information formats. (Note, Exhibits D and E do not use All Caps in headings)

The reason it makes little difference if the brand name is in All Caps, is that it is usually one word, and the reader quickly skims the All Caps single word knowing it is the brand name. In effect, All Caps in this case acts like a coding cue that actually facilitates reading. However, a sentence in All Caps is not used the same way by readers, and for the above mentioned reasons is not preferred.

## **12. Poison Control Warning Should Be Required in the Brief Summary; the Pregnancy Warning Should Appear in the Same Section of the Brief Summary.**

---

<sup>29</sup> An ascender is that part of the lower case letter that ascends above the main body of the letter. Lower case letters with ascenders include: b,d,f,h,k,l,t. Descenders are those parts of a letter that descend below the lower aspect of the body of the letter. Lower case letters with descenders include: g,j,p,q, y.

<sup>30</sup> Food and Drug Administration. Over-The-Counter Human Drugs; Labeling Requirements; Final Rule. Federal Register: March 17, 1999;(64):13253-13303.

The examples of current Brief Summaries found as Exhibits A-E do not contain a poison control warning. OTC drug products bear the warning by regulation: “Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.”

The Center supports a poison control warning in the Brief Summary, since the Brief summary is intended to be used prior to first use and again each time the product is refilled because new warnings may be added (e.g., see Exhibits C, D, E at top of Brief Summaries). The timing of intended use of the Rx drug information in the Brief Summary is identical to the timing of intended use of the “OTC “Drug Facts” label. Since Rx and OTC medicines are used widely in households with children, there is no cogent rationale for not including a poison control warning in the Brief Summary.

Furthermore, since the pregnancy/nursing warning information and the poison control warning appear in the same general location on the OTC “Drug Facts” label, for consistency they should appear in similar fashion in the Brief Summary (e.g., as shown in Exhibit F, a model of the revised third generation Brief Summary).

An exception to this may be when there is a compelling reason to highlight a pregnancy/nursing warning as a special warning at the top of all warnings (e.g., as in the case for the seizure warning in Exhibit F). Further, any additional warnings or information, for example concerning a pregnancy registry, would then logically appear with the pregnancy warning. Again, consistency in placement of information across OTC label and Rx Brief Summaries has the potential to make access of similar information easier for the consumer.

13. **“Drug Facts” with “Highlights” and “Rx Only” Should Be the Leading Terms at the Top of the Brief Summary (Exhibit F), and Placement of the Notice Concerning Availability of Complete Product Information and the Notice of Toll Free Number Availability Should Appear at the Top of the Brief Summary.**

The Center agrees that a notice concerning the fact that the Brief Summary does not contain all information about the product and the availability of a toll free number <sup>31</sup> should appear in the Brief Summary. It seems logical that this information would appear at the very top of the Brief Summary as noted in Exhibit F and excerpted from Exhibit F below. It would be important as the potential user reads the information for that reader to understand s/he is reading a portion of available information about the drug.

The Center further recommends the use of an asterisk after the topic heading Highlights to link this word to its intended meaning two lines below. It is unclear to what extent consumers understand the word Highlights to describe a revised version of the Brief Summary that would contain only the most serious and most common side effects and other information. The use of an asterisk for Highlights in close proximity to the explanatory sentence (e.g., Exhibit F) would address this concern.

<b>Drug Facts</b>	<b>Highlights*</b>	<b>Rx only</b>
<small>Before you start taking BRANDNAMEMED and again each time you get a refill, read this information, since new warnings or other information may be added. * This does not contain all of the information about BRANDNAMEMED. For additional information, contact 1-TOL-LFR-EEEE</small>		
<small>Active ingredient (in each tablet) "INGREDIENTNAME as the salt" XXXmg or YYY mg .....</small>		<small>Purpose Antidepressant</small>
<b>[See Exhibit F for remainder of information in Brief Summary]</b>		

<sup>31</sup> It is accurate to describe the “1-800” number as a toll free number, since business concerns can have toll free numbers without the “800” number per se.

#### 14. Simplification of Terms Is Essential for Clear Health Communications.

FDA should cross-reference the Final Guidance or Final Rule to the list of interchangeable terms created by FDA in relation to the OTC “Drug Facts” label. These interchangeable terms are intended to simplify the language used in OTC labeling, and the same principles would apply to Rx labeling intended for the consumer, i.e., the Brief Summary.

#### D. Conclusion

In conclusion, the UCSF Center for Consumer Self Care favors consumer access to important health information relating to the safe and effective use of medications.

The Center agrees with FDA’s intent to create a consumer-friendly DTC Brief Summary - one that would be more likely to be read by the consumer. However, the Center notes that FDA has not answered a fundamental question about its approach to revising the Brief Summary: *Why is FDA taking different approaches to the consumer labeling of Rx and OTC drug products, when the target populations for both categories of medicines are the same - i.e., the consumer?*

The Center has offered a rationale for why FDA should adopt essentially all of the format and content approaches that were adopted into the final regulation for the OTC “Drug Facts” label, and has also offered specific recommendations pertinent to such an approach.

The Center encourages the agency to move in the direction of consumer-centered health communication, and would be pleased to interact with the agency to further address this and other similar issues.

Sincerely,



R. William Soller, Ph.D.  
Executive Director  
UCSF Center for Consumer Self Care

Clinical Professor of Pharmacy  
Department of Clinical Pharmacy  
UCSF School of Pharmacy  
415-502-7633

**Exhibits:**

- A. Rx consumer advertisement and Rx Brief Summary for Nexium® in *Time Magazine*, April 26, 2004.
- B. Rx consumer advertisement and Rx Brief Summary for Allegra® in *Newsweek*, April 26, 2004.
- C. Rx consumer advertisement and Rx Brief Summary for Levitra® in *Kiplinger's Personal Finance*, May 2004.
- D. Rx consumer advertisement and Rx Brief Summary for Wellbutrin XL® in *U.S. News & World Report*, April 26, 2004.
- E. Rx consumer advertisement and Rx Brief Summary for Strattera® in *U.S. News & World Report*, April 26, 2004
- F. Model Brief Summary in OTC "Drug Facts" Format