Performance Review initiative implementing the President's Grassroots Regulatory Partnership Meetings. These workshops are made possible by funding from the Office of Women's Health.

Dated: August 14, 1995.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

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BILLING CODE 4160–01–F

[Docket No. 95N–0259]

Over-the-Counter Drug Labeling; Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public hearing to discuss over-the-counter (OTC) drug labeling issues. The purpose of the hearing is to solicit information and views concerning various aspects of OTC drug labeling design that would improve the communication of information to consumers. The agency is particularly interested in hearing from individuals, industry, consumer groups, health professionals, and researchers with expertise in communicating information to consumers, skills in design, and insight into consumer needs and desires with respect to OTC drug labeling. In addition, the agency is soliciting written comments and/or data on the costs and benefits of an improved labeling format.

DATES: The public hearing will be held on September 29, 1995, from 8 a.m. to 3 p.m. Mail or FAX notices of participation to be received by FDA by September 15, 1995. The Nonprescription Drugs Advisory Committee will meet from 3 p.m. to 4 p.m., following the public hearing. This meeting will be open to the public. Written comments will be accepted until December 29, 1995.

ADDRESSES: The public hearing will be held at the Parklawn Bldg., conference rooms D and E, 5600 Fishers Lane, Rockville, MD 20857. Submit written notices of participation and comments to the Dockets Management Branch (HFA–305), ATTN: OTC Drug Labeling Hearing, Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, or FAX written notices of participation and comments to the Dockets Management Branch, ATTN: OTC Drug Labeling Hearing, 301–594–3215. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with Docket No. 95N–0259. Transcripts of the hearing will be available for review at the Dockets Management Branch (address above). Information specified in this notice can be received by calling 301–594–5000 or sending a self-addressed stamped envelope with your request to the contact person listed below.

FOR FURTHER INFORMATION CONTACT: Michael D. Kennedy, Center for Drug Evaluation and Research (HFD–820), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20857, 301–594–1006.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Federal Food, Drug, and Cosmetic Act (the act), FDA has the responsibility to help ensure the safety and effectiveness of OTC drug products and to regulate their labels and labeling. The agency is engaged in an ongoing comprehensive review of the thousands of OTC drug products available to consumers without a prescription. As a result of that review, the agency has required, through notice-and-comment rulemaking, specific language to be included in the labeling of many OTC drug products, which describes the uses, directions, warnings, drug interactions, precautions, active ingredients, and other information that a consumer would need to know to use the product safely and effectively.

With escalating health care costs and the OTC availability of more products once obtainable only by prescription, self-medication is on the rise. Consequently, it is increasingly important that consumers read, understand, and behave in accordance with the information on OTC drug labels and labeling.

FDA regulations require that the OTC drug product labeling present and display information in such a manner as to render it "likely to be read and understood by the ordinary individual, including individuals of low comprehension, under customary conditions of purchase and use."[1] (21 CFR 330.10(a)(4)(v)). Despite this regulation, many consumers have complained that OTC drug labels are difficult to understand and that the print size is too small. For example, in 1991, FDA received a citizen's petition requesting regulatory standards for the print size and style of OTC drug product labeling. In the **Federal Register** of March 6, 1991 (56 FR 9363), the agency sought comments on this petition and other issues related to label legibility and readability. FDA received many comments criticizing the print size and complexity of current OTC drug labels and labeling.

The Nonprescription Drug Manufacturers Association (NDMA) has developed "Label Readability Guidelines" (NDMA Guidelines) for its members to use for guidance in designing OTC drug labels. These guidelines have served to provide advice on improving the legibility of OTC drug labeling. Copies of the NDMA guidelines are available from FDA by calling or writing the contact person listed above. FDA commends the drug industry for recognizing the need to improve OTC drug labeling features and for initiating voluntary readability guidelines. FDA, however, is firmly committed to further improving OTC drug labels and labeling and making them easier to read and understand. To date, the agency primarily has worked with manufacturers and consumers in this effort. In January 1995, FDA staff served as chairpersons and participated in a workshop with the Drug Information Association to discuss OTC drug labeling. The workshop was attended by consumers, industry, government officials, and academicians. The purpose was to explore perspectives on how to communicate OTC drug information more effectively to consumers through product labeling.

As part of this ongoing effort to improve OTC drug labeling, FDA is examining different formats that could be used to communicate drug information to consumers in a more effective manner. FDA is now also examining the question of whether a standardized format would aid in achieving the goals of improved communication. The Part 15 hearing announced in this notice is intended to seek public comment on various issues specifically related to the format of OTC drug labeling. In order to further understand consumer needs for OTC label design, FDA is also seeking public comments regarding consumer use and behavior related to OTC drug labeling.

The agency also recognizes that the terms and text required on OTC drug labeling could be improved to make the information easier to understand. The agency intends to hold one or more public meetings in the near future to discuss these issues.

[1] Consistent with the act, "labeling" refers to "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)).

II. Scope of the Hearing

In light of the many complex scientific and public health issues involved in communicating OTC drug information to consumers, FDA is soliciting broad public participation and comment on OTC drug labeling format issues and information regarding consumer use and behavior related to OTC drug labeling. The agency encourages individuals, industry, consumer groups, health professionals, and researchers with particular expertise in this area, as well as other interested persons, to respond to this notice. The agency strongly encourages persons who cannot attend the hearing to send information relevant to the topics and questions listed below to the Dockets Management Branch (address above). Comments should be identified with Docket No. 95N–0259.

Topics and questions to be considered during the hearing include:

A. Consumer Use of OTC Drug Labeling

(1) What information is available that characterizes consumer use of OTC drug labeling? For example, surveys and studies that require consumers to maintain diaries about their choice and use of OTC drugs have been performed to measure consumer use of OTC drugs. To what extent do these and other studies indicate the sources of information consumers use, such as OTC drug labeling, when deciding whether to use an OTC drug product (rather than consulting a physician or trying a nondrug remedy)?

(2) What studies exist describing whether consumers understand product labeling that may be applicable to OTC drug products (e.g., information provided on or with consumer products other than OTC drug products)? To what extent do consumers rely on OTC drug labeling information when choosing among competing products and when actually using an OTC drug product (e.g., consulting directions for use)?

(3) How would one expect label usage to vary with the type of product and consumer characteristics that affect the communication of information, such as literacy level, vision ability, etc.?

B. Legibility of OTC Drug Labeling

(1) What features of OTC drug labeling design should be considered to assure that labeling is legible to consumers? Should a performance standard be used to assure legibility (for example, should labeling be considered acceptably legible only if a certain percentage of consumers with defined vision ability, under defined lighting levels, correctly perceive a predetermined level of labeling information)?

(2) Currently, there are no required minimum standards for type size or other label design features for OTC drug labeling. Section 502(c) of the act (21 U.S.C. 352(c)) states that the information must appear with such "conspicuousness * * * as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase * * *." As stated earlier in this notice, many consumers have written the agency complaining that the type size on many OTC drug products is so small that they cannot read the information. Since then, the industry has taken strides to make OTC labeling more legible. The NDMA Guidelines set forth a voluntary minimum type size of 6 point for most OTC drug packages and 4.5 point for small packages. By comparison, newspaper type size is usually 9 to 10 point. Should OTC drug labeling on currently marketed products be more legible? Should FDA set minimum standards for type size for OTC drug labeling? If so, what should the standards be? Should the standards vary depending on the size of the label? What about particularly small packages?

(3) Currently, there are no required minimum standards for other factors that affect the communication of information on OTC drug labeling, such as color, contrast, type style, spacing, and white space. Should FDA set minimum standards for these features? If so, what should the standards be? In addition, there are no standards for factors that affect readability, such as use of uppercase and lowercase letters, instead of all uppercase, and use of boldface and other highlighting techniques. Should FDA set minimum standards for these features? If so, what should they be? What other drug labeling design features are needed to improve legibility (e.g., would reducing the amount of information on the label improve information communication by allowing for increased white space between lines of text, layout, or design of information)?

(4) How do label features, such as type size, type style, contrast, spacing, etc., influence consumers' attention to and "willingness to read" the OTC drug labeling? How critical is this aspect for information processing (i.e., how do OTC drug labeling design features influence consumer motivation to read the label)?

C. OTC Drug Labeling Design Features

(1) The agency recently imposed a standardized format for labels on food products, pursuant to the Nutrition Labeling and Education Act of 1990. The purpose of the standardized format is to enable the public to readily observe and comprehend nutrition information and to understand its relative significance in products. FDA recognizes that the type of information listed on food labels is different in some respects from the type of information on OTC drug labeling. The agency also recognizes that standardization may inhibit flexibility in designing labeling. Nonetheless, FDA believes that standardization of format would help consumers know what information to look for and where to find it. What benefits to the communication of information would a uniform, standardized OTC drug labeling format provide to the consumer? What other benefits would a uniform, standardized format provide to the consumer?

(2) FDA recently approved switches from prescription to OTC status for two similar drugs intended to treat heartburn and acid indigestion. Each product's labeling was designed by the manufacturer with the intention of providing maximum communication of information, yet the labeling formats used for the two products are very different. Also, a major OTC drug pharmaceutical company recently has redesigned its labels, using a different format. (Examples of these labels are available from FDA by calling or writing the contact person listed above.) Is it desirable to have a uniform format for OTC drug labeling to convey drug information or should manufacturers have the flexibility to utilize a few different formats or should any format be acceptable to convey this information?

(3) If the OTC drug labeling format were standardized, what features should be made consistent on all labeling (e.g., order of information, major headings or subheadings for information, use of lines or boxes around information, certain labeling statements)?

(4) Headings are often used to signal where particular information can be found. If OTC drug labeling were standardized, what headings are suitable for the information placed on the OTC drug label? Current headings use "key words," such as "active ingredients," "uses," "directions," "warnings," "inactive ingredients." Are key word headings suitable for OTC drug labeling? Would different headings be desirable, such as those in "Question and Answer" style, (e.g., "What is in [name of drug]?," "What is [name of drug] used for?" "How do I use [name of drug]?" "What should I be aware of about [name of drug]?" "When should I not use [name of drug]?") Considering size constraints of OTC drug labels, should the information required in OTC

drug labeling have a title such as "DRUG FACTS" to distinguish it from other information in the labeling that is not required, yet is useful for the consumer, e.g., claims of pleasant taste, 1–800 telephone number for information, money back guarantee information?

(5) Is the order of information placed on the label important? If so, if OTC drug labeling format were standardized, what order of information is most appropriate? (e.g., active ingredient, indications for use, directions for use, warnings, precautions, drug interactions, inactive ingredients, storage information, description of tamper resistant feature(s), 1–800 telephone number, UPC bar code)

(6) Symbols, pictograms, and icons that describe the text are sometimes used on OTC drug products to call attention to, or represent, certain information about the product. For example, to call attention to the standard warning "As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product," some manufacturers place next to the text a pictogram, which is a circle enclosing a silhouette of a pregnant woman with a line crossing the circle. This pictogram, however, could be interpreted to mean that the product prevents pregnancy. Thus, pictograms and icons may or may not be clear in their representation and may confuse the consumer. If the OTC drug labeling format were standardized, are there any particular pictograms and icons that should be used on OTC drug labeling? If used, how can consumer confusion as to their meaning be reduced?

(7) If OTC drug labeling format were standardized, should different types of information be separated in the labeling, using techniques such as boxing and bold lines? If so, where and when should boxes/lines be used? How would distinguishing between different types of information in this way benefit consumers?

(8) Should any other features be considered for standardization?

(9) In 1994, FDA staff from the Office of OTC Drug Evaluation presented an early prototype format for OTC drug labeling to FDA's Nonprescription Drugs Advisory Committee for comment. Copies of some mock-ups using the prototype format are available by calling or writing the contact person listed above. What features of the format are desirable? What features of the format could be improved?

D. Consumer Comprehension

(1) Even if consumers can perceive and are willing to read OTC drug labeling, they may not comprehend the content of this labeling. What design features need to be considered to make labeling information understandable?

(2) A number of guidances for designing labeling text are available, including test methods for evaluating readability, computer programs for improving grammar, and manuals for labeling format design are available. How should these guidances be used to design comprehensible text for OTC drug labeling? To what extent can one rely on these guidances to assure consumer comprehension?

(3) For certain drug products that have been switched from prescription to OTC status, the agency has asked the applicant to conduct studies of consumer comprehension of the proposed OTC drug labeling prior to approval of the switch. What testing methods are most useful for these types of comprehension studies?

E. Behavioral Issues

(1) As more prescription drug products are considered for OTC switches, consumers are being asked to make more complicated judgments about the appropriateness of these products for their personal use. For example, certain products are approved for OTC use only for recurrence of a condition that was initially diagnosed by a physician. To what extent can OTC drug labeling influence consumer judgments and behaviors that are necessary for the safe and effective use of these products? Does OTC drug labeling need to contain persuasive messages to encourage behavioral compliance with the directions for use?

(2) How can FDA be assured that the labeling is sufficient to ensure safe and effective use of the OTC drug product? What types of testing methods need to be used, and under what conditions, to measure the ability of OTC drug labeling to communicate important information to consumers and influence behavior?

(3) Since consumers vary considerably in their literacy level and in their ability to read and understand OTC drug labeling, how can FDA be assured that the effects of any labeling studies are generalizable to the population of potential users of the product? What additional consumer characteristics need to be considered to assure label comprehension and usage measures are applicable to the universe of consumers?

III. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with 21 CFR part 15. The presiding officer will be the Commissioner of Food and Drugs or his designee. The presiding officer will be accompanied by a panel of Public Health Service employees with relevant expertise.

Persons who wish to participate in the part 15 hearing must file a written or facsimile notice of participation with the Dockets Management Branch (address or FAX number above) by September 11, 1995. To ensure timely handling, the outer envelope should be clearly marked with Docket No. 95N–0259 and the statement "OTC Drug Labeling Hearing." Groups should submit two copies. The notice of participation should contain the speaker's name, address, telephone number, FAX number, business affiliation, if any, a brief summary of the presentation, and approximate amount of time requested for the presentation.

The agency requests that persons or groups having similar interests consolidate their presentations and present them through a single representative. FDA will allocate the time available for the hearing among the persons who properly file notices of participation. If time permits, FDA may allow participation at the conclusion of the hearing from interested persons attending the hearing who did not submit a written notice of participation.

After reviewing the notices of participation and accompanying information, FDA will schedule each appearance and notify each participant by mail, telephone, or FAX, of the time allotted to the person and the approximate time the person's presentation is scheduled to begin. The hearing schedule will be available at the hearing. After the hearing, the schedule will be placed on file in the Dockets Management Branch (address above) under Docket Number 95N–0259.

Under § 15.30(f), the hearing is informal and the rules of evidence do not apply. The presiding officer and any panel members may question any person during or at the conclusion of their presentation. No other person attending the hearing may question a person making a presentation or interrupt the presentation of a participant.

Public hearings under part 15 are subject to FDA's guideline (21 CFR part 10, subpart C) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings. Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The

hearing will be transcribed as required in § 15.30(b). Orders for copies of the transcript can be placed at the meeting or through the Dockets Management Branch (address above).

Any disabled persons requiring special accommodations in order to attend the hearing should direct those needs to the contact person listed above.

To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

To permit time for all interested persons to submit data, information, or views on this subject, the administrative record of the hearing will remain open following the hearing until December 29, 1995.

IV. Additional Request for Information

In order to assess the costs and benefits of enhanced OTC drug product labeling, written submissions to FDA on the following topics would be helpful:

(1) How frequently do companies reprint OTC drug product labels and labeling? How frequently are labels redesigned?

(2) What are the itemized costs involved in changing OTC drug labels and labeling (e.g., design, plate, reprinting, additional colors)?

(3) If FDA were to propose a new OTC drug labeling format, what strategies could be used to lessen the cost to industry? For example, what lead time would allow manufacturers to use up existing labeling inventories?

(4) What are the benefits to consumers from improvements in OTC drug labeling?

Written comments addressing cost components should address, where applicable, one-time versus annual costs, differences in brand versus private-label costs, and implications for small businesses. The agency is most interested in cost data expressed in dollars, staff hours, and personnel (professional, technical, or support). Quantitative measures of benefits are considered most desirable, but discussions of anecdotal and/or qualitative benefits are also welcomed. Submit comments to the Dockets Management Branch (address above) identified with Docket No. 95N–0259.

Dated: August 10, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–20245 Filed 8–15–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95N–0227]

Direct-to-Consumer Promotion; Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public hearing regarding direct-to-consumer promotion of prescription drugs. The purpose of the hearing is to solicit information from, and the views of, interested persons, including health care professionals, scientists, professional groups, and consumers, on the issues and concerns relating to the promotion of prescription drug products directly to consumers through print, broadcast, and other types of media. FDA is particularly interested in hearing the views of the groups most affected by direct-to-consumer promotion, including patients, caretakers, physicians, physicians' assistants, nurses, pharmacists, managed care organizations, and insurers.

DATES: The public hearing will be held on October 18, 1995, from 8:30 a.m. to 5:30 p.m., and October 19, 1995, from 8:30 to 12:30 p.m. Submit written notices of participation by September 15, 1995. Written comments will be accepted until December 29, 1995.

ADDRESSES: The public hearing will be held at the Quality Hotel—Silver Spring, 8727 Colesville Rd., Silver Spring, MD. Submit written notices of participation and comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with docket number 95N–0227. Transcripts of the hearing will be available for review at the Dockets Management Branch (address above).

FOR FURTHER INFORMATION CONTACT: Lee L. Zwanziger, Center for Drug Evaluation and Research (HFD–9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4695.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Federal Food, Drug, and Cosmetic Act (the act), FDA has responsibility for regulating the labeling and advertising (promotional activities) for prescription drugs. Under section 201(m) of the act (21 U.S.C. 321(m), labeling is defined to include all "written, printed, or graphic" materials "accompanying" a regulated product. The Supreme Court has agreed with the agency that this definition is not limited to materials that physically accompany a product. The Court has deemed the textual relationship between the materials and the products to be fundamental (*Kordel* v. *United States*, 335 U.S. 345, 349–350 (1948)). In its regulations, FDA has given examples of things that it regards as labeling, including brochures, mailing pieces, calendars, price lists, letters, motion picture films, sound recordings, and literature (§ 202.1(l)(2) (21 CFR 202.1(l)(2)). Although the act does not define what constitutes a prescription drug "advertisement," FDA generally interprets the term to include information (other than labeling) that is sponsored by a manufacturer and is intended to supplement or explain a product. This includes, for example, "advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems" (§ 202.1(l)(1)).

If an activity or material is considered to be either advertising or labeling, it must meet certain requirements. Labeling must contain adequate directions/information for use that is the "same in language and emphasis" as the product's approved or permitted labeling (21 U.S.C. 352(f)) and 21 CFR 201.100(d)). This requirement is generally fulfilled by including the full approved labeling for the product (the "package insert") with the promotional materials. The act specifies that, in addition to the identity of the product and its quantitative composition, advertisements must contain "other information in brief summary relating to side effects, contraindications, and effectiveness * * *"(21 U.S.C. 352(n)). FDA further defines this latter requirement in § 202.1(e). This requirement is generally fulfilled by including the sections of the approved labeling that discuss the product's adverse event profile, contraindications, warnings, and precautions. In addition, the act and regulations specify that drugs are deemed to be misbranded if their labeling or advertising is false or misleading in any particular or fails to reveal material facts (21 U.S.C. 352(a) and 321(n) and § 202.1(e)).

A. History of Direct-to-Consumer Promotion

The practice of promoting prescription drug products directly to consumers began to gain popularity in the early 1980's. Until that time, drug