Board of Governors of the Federal Reserve System, February 28, 1991.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 91-5203 Filed 3-5-91; 8:45 am]

BILLING CODE 6210-01-M

GENERAL SERVICES ADMINISTRATION

Information Resources Management Service: Federal Telecommunications Standards

ACTION: Notice of adoption of standard.

SUMMARY: The purpose of this notice is to announce the adoption of a Federal Telecommunications Standard (FED-STD). FED-STD 1016, "Telecommunications: Analog to Digital Conversion of Radio Voice by 4,800 Bit/second Code Excited Linear Prediction (CELP)" is approved by the General Services Administration and will be published.

FOR FURTHER INFORMATION CONTACT: Mr. Robert M. Fenichel, Office of Technology and Standards, National Communications System, telephone (703) 692-2124.

SUPPLEMENTARY INFORMATION:

1. The General Services Administration (GSA) is responsible, under the provisions of the Federal Property and Administrative Services Act of 1949, as amended, for the Federal Standardization Program. On August 14, 1972, the Administrator of GSA designated the National Communications System (NCS) as the responsible agent for the development of telecommunications standards for NCS interoperability and the non-computer communication interface.

2. On September 22, 1989, a notice was published in the Federal Register (54 FR 39066) that a proposed Federal Telecommunications Standard 1016 entitled "Telecommunications: Analog to Digital Conversion of Radio Voice by 4,800 Bit/second Code Excited Linear Prediction (CELP)" was being proposed for Federal use.

3. The justification package as approved by the Director, Office of Science and Technology Policy (OSTP), Executive Office of the President was presented to GSA by NCS with a recommendation for adoption of the standard. These data are a part of the public record and are available for inspection and copying at the Office of Technology and Standards, National Communications System, Washington, DC 20305-2010.

4. Interested parties may purchase the standard from GSA, acting as agent for the Superintendent of Documents. Copies are for sale at the GSA Specifications Unit (WFSIS), room 6039, 7th and D Streets, SW., Washington, DC 20407; telephone (202) 708-9205.

Dated: February 14, 1991.

Thomas J. Buckholtz,

Commissioner, Information, Resources Management Service.

[FR Doc. 91-5241 Filed 3-5-91; 8:45 am]

BILLING CODE 6820-25-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 90P-0201]

Rin 0905-AA06

Print Size and Style of Labeling for Over-the-Counter Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on a citizen petition filed by Pharmacists Planning Service, Inc., requesting regulatory standards for the print (optimum size and style) of over-the-counter (OTC) drug product labeling in order to maximize readability and legibility for persons with impaired or deteriorating vision.

DATES: Comments by June 4, 1991.

ADDRESSES: Submit written requests for single copies of the citizen petition to the Division of Over-the-Counter Drug Evaluation (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on print size and style of labeling for OTC drug products to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: The Pharmacists Planning Service, Inc. (the petitioner), 200 Gate Five Rd., Sausalito, CA 94966, has petitioned FDA under the provisions of § 10.30 Citizen petition (21 CFR 10.30) to establish regulatory standards for the print (optimum size and style) of OTC drug product labeling to maximize readability and legibility.

I. Summary of Petitioner's Views

The following narrative summarizes the information and arguments presented by the petitioner in support of its proposal. The material included in the narrative does not necessarily represent the views of the agency.

The petitioner stated that there is a need to institute larger print size on the packaging of OTC drug products, and to establish standards for the optimum size and style of print to be used for the labels and other printed material packaged with OTC drug products. These standards are needed in order to maximize readability of the print for persons with deteriorating vision, and because most people (especially the elderly) are unable to read the small print that currently appears on some OTC drug product labeling.

The petitioner stated that its request was being made pursuant to California Assembly Bill (AB) 2713 for the following reasons:

(1) Medication misuse and abuse is a serious and costly problem to patients, health providers, health care insurance plans, and local, State, and Federal governments.

(2) Prescription drugs continue to be switched to OTC status along with their attendant side effects and cautions on use.

(3) OTC drugs are marketed in containers of all shapes and sizes, and the labeling bears instructions, cautions, and side effects associated with their use.

(4) Most people, particularly the elderly, are unable to read the small print, and vital information is buried with other information that is required by FDA.

The petitioner also stated that the need for this type of additional regulation to safeguard the health, welfare, and safety of the public has been documented, and that "more than 240,000 older adults were hospitalized due to adverse drug reactions, mixing OTC drugs, which are available through sources other than a qualified health professional, and through lack of medical/pharmaceutical information on the proper method of administration of these medications." The petitioner also argued that there is no economic impact involved with its citizen petition, but that there would be a "$10 billion" savings in hospital costs. (Note: The petitioner provided a copy of the original California bill AB 2713;

however, there is a more current amended version (Ref. 1) that was enacted on September 12, 1990.)

II. Current Regulatory Policy

Currently, there are no statutory or regulatory requirements that specifically address the print size and style of the labeling of OTC drug products. Section 502 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352) states that

> A drug * * * shall be deemed to be misbranded * * * (c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs * * * in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

Implementing regulations in 21 CFR 201.15, which address the prominence of required label statements for drugs, describe a number of situations in which information on a drug product's label may lack the prominence and conspicuousness required by section 502(c) of the act. Paragraph (a)(6) of § 201.15 identifies the following reasons: "Smallness or style of type in which such word, statement, or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed, or graphic matter." However, no further requirements appear as to the size or style of type that is to be used.

Other agency regulations discuss various print size and style requirements. For example, the statement of identity of an OTC drug product is required to be presented in boldface type on the principal display panel, in a size reasonably related to the most prominent printed matter on such panel, and in lines generally parallel to the base on which the package rests as it is designed to be displayed. (See 21 CFR 201.61(c).) In some instances, the agency has required that warnings for certain OTC drug products appear in boldface type. For example, certain warnings for OTC bronchodilator drug products in 21 CFR 341.76(c)(6)(i) and (c)(6)(ii) are required to appear in boldface type. However, none of the existing regulations specifically address print size or style that is to be used.

III. Consumer Complaints; Professional Views

Based on a syndicated article that appeared in a newspaper column entitled "Peop'e's Pharmacy" (Refs. 2 and 3), a number of consumers (Ref. 4) wrote to FDA recently and complained about the readability of OTC drug product labeling. Many individuals complained about the small print size, and some were concerned about the style and color contrast. Several consumers specifically mentioned problems with reading the small print of OTC ophthalmic drug products. Questions were also raised about the safety of small print size because poor label legibility may result in adverse drug reactions due to improper dosing. Several consumers claimed they had such an experience. Many people complained that even though with corrective lenses they have "20/20 vision" they still need a magnifying glass to read the labels. Comments about print size have been received by the agency in a number of OTC drug rulemakings (e.g., OTC skin protectant drug products (February 15, 1983; 48 FR 6820 at 6830); OTC ophthalmic drug products (March 4, 1988; 53 FR 7076 at 7079)). A professional pharmaceutical group has recognized that the visually impaired, including many elderly persons, may have trouble reading medication labels, especially on smaller packages. This group has recommended Federal legislation similar to California AB 2713 to increase the optimum size and style of print to improve the readability of OTC drug labels (Ref. 5).

IV. California Legislation

On September 12, 1990, the Governor of the State of California signed AB 2713 to amend the Health and Safety Code regarding the labeling of nonprescription drug products (Ref. 1). Section 1 of the bill states that printed materials on labels and notices packaged with nonprescription drugs may be difficult to read, presenting a potential danger to the health and safety of customers. Therefore, every effort should be made to print these materials in a manner which makes them more comprehensible. Section 2 of the bill adds the following to the State's Health and Safety Code: (1) Manufacturers of nonprescription drugs which are sold in the State of California shall evaluate and may modify the labeling of nonprescription drugs to maximize the readability and clarity of label information, in both the cognitive and visual sense; (2) the Nonprescription Drug Manufacturers Association (NDMA) shall report on a quarterly basis to, and seek advice periodically from, the California State Department of Health Services, consumer groups, health professionals, and drug manufacturers regarding the progress made by the nonprescription drug industry with respect to the readability and clarity of labeling information; and (3) the director of the California State Department of Health Services, shall report to the legislature on or before December 3, 1993, regarding the progress made by the nonprescription drug industry with respect to the readability and clarity of labeling information. The bill further states that these provisions shall be repealed as of January 1, 1994.

V. Nonprescription Drug Manufacturers Association Action

FDA is aware that NDMA has endorsed the California legislation, and, in recognition of label reading difficulties, has appointed a task force on labeling to: (1) Explore the many aspects of label readability and legibility, and (2) evaluate the need and opportunity to make labels more easily read and understood by the public (Ref. 6). The task force is responsible for making recommendations to the NDMA Board and Association members on options to achieve such labeling, including type-size, print, style, color, contrast, package inserts, and special larger size packages. NDMA has also issued guidelines for industry entitled "Points for Consideration in Examining Product Labels for Readability and Legibility," (Ref. 7). These guidelines have been mailed to all NDMA member companies asking that they review their product line against six criteria to see if improvements can be made in the legibility of product labeling. The six criteria are as follows:

1. *General legibility.* Read your own labels. Examine the presentation of your labeling information as would a consumer. Is it readable?

2. *Utilization of available space.* In some cases it may be possible to enlarge label type size by extending the copy into some of the existing "white space." Examine the location and placement of information. Review alternative approaches to maximizing available space allocation, including placement of directions, instructions, warnings, and precautions on more than one panel of exterior carton.

3. *Contrast and color.* Review not only the size and placement of information, but also review the utilization of color and contrast to emphasize and draw attention to labeling information. Highly contrasting copy/background colors are more legible than low contrast colors. Dark type on a light background is more legible than light-on-dark. The smaller the type, the greater the contrast should be. Consumers of all ages are more apt to read and understand label information presented in a sharp contrast.

4. *Style of print.* Examine possible variations in style of type and graphic presentation. Upper and lower case type is easier to read than all capitals. Plain block print is more legible than fancy type. Allow space between paragraphs and words. Indent, bold, and highlight information such that it will grab the attention of the consumer and focus attention on label information.

5. *Quality of print.* Size of type is not everything. The quality (sharpness) of print has a great effect on legibility. Different printing methods differ in quality, e.g., letterpress printing is usually sharper than offset. Thinner (less bold) type may appear sharper than bolder type.

6. *Package innovation possibilities.* Creative packaging can provide more space for information, allowing more flexibility in presentation of information. Think of ways that would assist a consumer in reading and understanding label information.

VI. Request for Comments

The petitioner, consumers, professional group, NDMA, and California legislation discussed above raise issues that need to be addressed before FDA can make a final decision on the feasibility of establishing a Federal regulation pertaining to print size and style of OTC drug labeling. In the past, FDA has encouraged manufacturers to include a statement on the product container label, carton, or package insert suggesting that the consumer retain the carton or package insert for complete information about the use of the product when all the required labeling does not appear on the product container label. Manufacturers are free to design ways of incorporating such labeling, e.g., by using flap, wrap-around, or fold-over labels or by redesigning cartons or containers to provide more label space with room for larger and more legible print. In an effort to determine whether further steps need to be taken and whether a consensus can be reached on the most practical manner of providing for OTC drug labeling that is easy to read, FDA is seeking public comments on the feasibility of establishing Federal regulations that deal with the print size and style of OTC drug labeling. FDA also intends to consider the recommendations of NDMA's task force. In addition, FDA is seeking public comments on whether any new labeling requirements would have a substantial economic impact because of the large number of manufacturers who might incur additional labeling expense. Therefore, in accordance with § 10.30(h)(3) (21 CFR 10.30(h)(3)), FDA is seeking public comments on the following questions before reaching any decision on the petition:

1. Are current print sizes, types, colors, contrasts, backgrounds, etc. of OTC drug labeling adequate in providing readable information for individuals with normal eyesight and for those with poor or deteriorating eyesight?

2. Should there be a mandatory minimum print size or other readability standard and, if so, what should it be? If the answer is yes, should this be established via a regulation or a guideline?

3. Should a package insert or larger carton be mandatory if a minimum print size standard is implemented, and because of package size, the manufacturer is unable to meet the specifications?

4. What impact would a Federal legibility/readability regulation have on State laws that relate to "slack-fill"?

5. What relevant data are available and what studies have been performed to determine optimum print size, background, contrast, etc. for package products?

6. What adverse effects have been documented that are associated with the inability or failure to read labels on OTC drug products?

7. Will the NDMA guidelines be effective and have a positive impact on labeling and, if so, are these guidelines adequate so that a Federal regulation or guideline is not needed?

The complete petition is on public display between 9 a.m. and 4 p.m., Monday through Friday, in the Dockets Management Branch. Requests for single copies of the petition may be submitted to the Division of OTC Drug Evaluation (address above).

Interested persons may, on or before June 4, 1991, submit to the Dockets Management Branch (HFA-305) (address above) written comments regarding this petition. Three copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. The petition, other information discussed above, and any comments received in response to this request for comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

If, after reviewing the comments and other information available, FDA concludes that the petition has sufficient merit, the agency will propose regulations or a guideline accordingly.

VII. References

(1) Assembly Bill (AB) 2713 State of California, in OTC Vol. 24, Docket No. 90P-0201, Dockets Management Branch.

(2) Copy of newspaper article from the "People's Pharmacy," King Features Syndicate, in OTC Vol. 24, Docket No. 90P-0201, Dockets Management Branch.

(3) Letter from W. E. Gilbertson, FDA, to J. and T. Graedon, the "People's Pharmacy," in OTC Vol. 24, Docket No. 90P-0201, Dockets Management Branch.

(4) Letters from consumers to FDA, in OTC Vol. 24, Docket No. 90P-0201, Dockets Management Branch.

(5) Comment No. C1, Docket No. 90P-0201, Dockets Management Branch.

(6) News release, Nonprescription Drug Manufacturers Association, Washington, July 23, 1990, in OTC Vol. 24, Docket No. 90P-0201, Dockets Management Branch.

(7) Letter from J. D. Cope, Nonprescription Drug Manufacturers Association, to W. E. Gilbertson, FDA, enclosing Nonprescription Drug Manufacturers Association's "Points for Consideration in Examining Product Labels for Readability and Legibility," in OTC Vol. 24, Docket No. 90P-0201, Dockets Management Branch.

Dated: February 25, 1991.

David A. Kessler,

Commissioner of Food and Drugs

[FR Doc. 91-5232 Filed 3-5-91; 8:45 am]

BILLING CODE 4160-01-M

Health Resources and Services Administration

Filing of Annual Report of Federal Advisory Committee

Notice is hereby given that pursuant to section 13 of Public Law 92-463, the Annual Report for the following Health Resources and Service Administration's Federal Advisory Committee has been filed with the Library of Congress:

Council on Graduate Medical Education

Copies are available to the public for inspection at the Library of Congress Newspaper and Current Periodical Reading Room, Room 1026, Thomas Jefferson Building, Second Street and Independence Avenue, SE., Washington, DC, or weekdays between 9:00 a.m. and 4:30 p.m. at the Department of Health and Human Services, Department Library, HHS North Building, Room G-619, 330 Independence Avenue, SW., Washington, DC, telephone (202) 619-0791. Copies may be obtained from: Carol S. Gleich, Ph.D. Executive Secretary, Council on Graduate Medical