DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0036]

Use of Color on Pharmaceutical Product Labels, Labeling and Packaging; Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Center for Drug Evaluation and Research (CDER) of the Food and Drug Administration (FDA) is announcing a public hearing on the current practice of applying color to pharmaceutical product packaging and labeling to help identify, classify, and differentiate those drug products. To date, there is little scientific evidence that applying color is effective in reducing medication errors. Furthermore, there is no validated scientific method to corroborate the benefits of using colors on pharmaceuticals in this fashion. FDA does not have a policy pertaining to the use of colors on drug product packaging. The purpose of the hearing is to obtain public input on the benefits and potential drawbacks of applying color to drug packaging and labeling to help identify, classify, or differentiate those products.

DATES: The public hearing will be held on March 7, 2005, from 8 a.m. to 4:30 p.m. Submit written or electronic notices of participation and comments for consideration at the hearing by February 11, 2005. Written or electronic comments will be accepted after the hearing until April 7, 2005. The administrative record of the hearing will remain open until April 7, 2005.

ADDRESSES: The public hearing will be held at Lister Hill Auditorium, Building 38A, on the campus of the National Institutes of Health, Bethesda, MD (Metro stop: Medical Center Station on the Red Line). Submit written or electronic notices of participation and comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852; e-mail *FDADockets@oc.fda.gov*; or on the Internet at *http://frwebgate.access.gpo.gov/cgi-bin*. Transcripts of the hearing will be available for review at the Division of Dockets Management and on the Internet at *http://frwebgate.access.gpo*, approximately 30 days after the hearing.

FOR FURTHER INFORMATION CONTACT: Mary C. Gross, Center for Drug Evaluation and Research (HFD–400), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3216, *grossm@cder.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The following color techniques are used on pharmaceutical products and medical devices:

• Color Coding—Color coding is the systematic standard application of color to aid in the classification and identification of drug products. A color coding system allows people to memorize a color and match it to its function.

• Color Differentiation—Color differentiation involves the use of color to make certain features on the package stand out or to help distinguish one item from another. The color itself is not a standard code that is applied systematically to classify and identify the product, as with color coding.

• Color Branding—Color branding is a newly applied concept introduced by a single manufacturer of insulin products. Color branding is used to differentiate one drug product from another and is managed by the individual

sponsor. The sponsor recommended this tool in an effort to minimize error between an insulin analogue and another product containing a mix of insulin analogues.

• Color Matching—Color matching is sometimes applied in an effort to reduce the risk of errors. For example, a medical device may have a blue plug that attaches to a blue receptacle and a yellow plug that attaches to a yellow receptacle. However, the colors have no special meaning beyond matching one item with another.

In the **Federal Register** of May 13, 1998 (63 FR 26694), FDA published a direct final rule entitled "Removal of Regulations Regarding Certification of Drugs Composed Wholly or Partly of Insulin." Included in the rule was the removal of § 429.12 (21 CFR 429.12) that contained a distinguishing color scheme for insulin products. At that time, the agency was favorably impressed with the cooperative effort between the insulin manufacturers and the International Diabetes Foundation (IDF) that resulted in a new color coding system in which each insulin product would be identified with a distinctive color. Although some insulin products have been approved with the IDF colors, the agency has not taken a position on whether to fully implement the IDF color scheme for insulin products, nor has FDA taken a public position on the acceptability of adopting any other color scheme currently in use.

A number of drug product and device manufacturers use color schemes as described previously in this document in an effort to facilitate the selection and dispensing of drugs. For example, ophthalmic, anesthetic, dental, and insulin drug products, as well as medical devices, all use color to classify, identify, or differentiate drugs among the same class or facilitate the correct use of medical devices. Individual practitioner groups often endorse the use

of colors to help differentiate among drugs. Many drugs are marketed with similar labeling and labels which contributes to an already complex prescribing and dispensing environment. Sight challenged ophthalmic patients count on color coding to identify their products. Patient safety groups, however, argue that broad application of color techniques is unproven, controversial, and could be a contributing factor in medication errors.[1]

II. Scope of the Hearing

FDA is interested in obtaining public comment on the following issues:

• How and under what circumstances has the use of color on pharmaceutical packaging and/or labeling demonstrated an improvement in patient care? If there is no discernible improvement, please describe what you consider to be deficiencies in the program.

• Are there specific classes of drugs where use of color has demonstrated value? Are there classes where use of color is a hindrance to public safety?

• Are there drug products currently marketed that do not use color but should use color to aid in identification of the drug? If so, how should color be used?

• How should the effectiveness of application of color on drug products be scientifically validated?

III. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs (the Commissioner) is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The presiding officer will be the Commissioner or his designee. The

[1]Citations regarding the role of color coding and medication error reduction may be accessed at Report 5 of the Council on Scientific Affairs (A–04) Full Text—The Role of Color Coding in Medication Error Reduction. The article is accessible at: *http://www.ama-assn.org/ama/pub/category/13662.html* (FDA has verified the Web site address but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

presiding officer will be accompanied by a panel of FDA employees with relevant expertise.

Persons who wish to participate in the part 15 hearing must file a written or electronic notice of participation with the Division of Dockets Management (see **ADDRESSES** and **DATES**). To ensure timely handling, any outer envelope should be clearly marked with the docket number listed in brackets in the heading of this notice along with the statement "Use of Color on Drug Product Packaging Hearing." Groups should submit two written copies. The notice of participation should contain the potential presenter's name; address; telephone number; affiliation, if any; the sponsor of the presentation (e.g., the organization paying travel expenses or fees), if any; a brief summary of the presentation; and the approximate amount of time requested for the presentation. The agency requests that interested persons and groups having similar interests consolidate their comments and present them through a single representative. After reviewing the notices of participation and accompanying information, FDA will schedule each appearance and notify each participant of the time allotted to the presenter and the approximate time that presenter's oral testimony is scheduled to begin. If time permits, FDA may allow interested persons attending the hearing who did not submit a written or electronic notice of participation in advance to make an oral presentation at the conclusion of the hearing. The hearing schedule will be available at the hearing. After the hearing, the schedule will be placed on file in the Division of Dockets Management (see **ADDRESSES**) under the docket number listed in brackets in the heading of this notice.

Under § 15.30(f), the hearing is informal, and the rules of evidence do not apply. No participant may interrupt the presentation of another participant.

Only the presiding officer and panel members may question any person during or at the conclusion of each presentation.

Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (21 CFR part 10, subpart C). Under § 10.205 (21 CFR 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 stipulated in § 15.30(b). The transcript will be available on the Internet at *http://www.fda.gov/ohrms/dockets*, and orders for copies of the transcript can be placed at the meeting or through the Division of Dockets Management (see **ADDRESSES**).

Any handicapped persons requiring special accommodations to attend the hearing should direct those needs to the contact person (see **FOR FURTHER INFORMATION CONTACT**).

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 these provisions as specified in § 15.30(h).

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic notices of participation and comments for consideration at the hearing (see **DATES**). Submit a single copy of written or electronic notices of participation and comments, or two paper copies of any mailed notices of participation and comments, 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. Received comments may be seen

in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 1/28/05

January 28, 2005.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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