

SUMMARY: The Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER), in collaboration with FDA's Office of Regulatory Affairs (ORA), Southwest Regional Office (SWRO), is announcing a public workshop entitled "FDA Drug Educational Forum." This public workshop is intended to provide information about FDA's premarket requirements to the drug industry, particularly small businesses, startups, and entrepreneurs.

Date and Time: The public workshop will be held on May 11, 2005, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Kansas City Health Department Auditorium, 2400 Troost Ave., Kansas City, MO 64108-2666. For directions to the facility, please call 816-513-6008, e-mail:

health@kcmo.org, or visit <http://www.kcmo.org/health.nsf/web/healthmap?opendocument>. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

Contact: David Arvelo or Cassandra Davis, Food and Drug Administration, 4040 N. Central Expressway, suite 900, Dallas, TX 75204-3128, 214-253-4952 or 214-253-4951, FAX: 214-253-4970, e-mail: oraswrsbr@ora.fda.gov.

Registration: Registration begins on April 6, 2005, and ends May 6, 2005. Registration is free. Seats are limited, please register as soon as possible. Space will be filled in order of receipt of registration. Those registered will receive confirmation. Registration will close after available space fills. Registration at the site will be based on space availability on the day of the event starting at 8 a.m.

If you need special accommodations due to disability, please contact David Arvelo or Cassandra Davis (see **CONTACT**) at least 7 days in advance.

Registration Form Instructions: To register, complete the following registration form and submit via:

- E-mail: oraswrsbr@ora.fda.gov,
- FAX: 214-253-4970, or
- Mail to: Food and Drug

Administration, Southwest Regional Office, Small Business Representative, 4040 N. Central Expressway, suite 900, Dallas, TX 75204-3128.

Name: _____

Company Name: _____

Mailing Address: _____

City: _____ State: _____

Zip Code: _____

Phone: () _____

Fax: () _____

E-mail: () _____

Transcripts: Transcripts of the public workshop will not be available due to the format of this workshop. Course handouts may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the public workshop at cost of 10 cents per page.

SUPPLEMENTARY INFORMATION: The public workshop is being held in response to the interest in the topics discussed from small drug manufacturers, startups, and entrepreneurs in the FDA Southwest Region area. FDA, CDER, and ORA present this public workshop to help achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which include working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. This is also consistent with the purposes of FDA's Regional Small Business Program, which are in part to respond to industry inquiries, develop educational materials, sponsor workshops and conferences to provide firms, particularly small businesses, with firsthand working knowledge of FDA's requirements and compliance policies. This public workshop is also consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121), as outreach activities by Government agencies to small businesses.

The goal of the public workshop is to present information that will enable manufacturers and regulated industry to better comply with the new drug approval process (21 CFR part 314). Information presented will be based on agency position as articulated through regulation, compliance policy guides, and information previously made available to the public. Topics to be discussed at the public workshop include the following: (1) Planning for successful, efficient, pharmaceutical product approval; (2) current challenges and concerns for generic abbreviated new animal drug applications (ANDAs); (3) regulatory aspects and challenges in the development of over-the-counter (OTC) Drugs; (4) the basics of chemistry, manufacturing and control; (5) FDA 483

issues; (6) mastering regulatory compliance; and (7) incentives for small businesses.

Dated: January 28, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05-2098 Filed 2-2-05; 8:45 am]

BILLING CODE 4160-01-S

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.gov>, 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?

¹Citations 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**.)

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 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: January 28, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05-2094 Filed 1-31-05; 3:37 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Infant Mortality; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

Name: Advisory Committee on Infant Mortality (ACIM).

Dates and Times: March 1, 2005, 9 a.m.–5 p.m. March 2, 2005, 8:30 a.m.–3 p.m.

Place: Sheraton National Hotel, 900 South Orme Street, Arlington, Virginia 22204, (703) 521-1900.

Status: The meeting is open to the public with attendance limited to space availability.

Purpose: The Committee provides advice and recommendations to the Secretary of Health and Human Services on the following: Department programs that are directed at reducing infant mortality and improving the health status of pregnant women and infants; factors affecting the continuum of care with respect to maternal and child health care, including outcomes following childbirth; strategies to coordinate the variety of Federal, State, local and private programs and efforts that are designed to deal with the health and social problems impacting on infant mortality; and the implementation of the Healthy Start program and *Healthy People 2010* infant mortality objectives.

Agenda: Topics that will be discussed include the following: Improving Perinatal Data; Neonatal Intensive Care and Ethical Issues; and Provider Reimbursement Issues. Substantial time will be spent in small group and full Committee discussions aimed at formulating the ACIM issues agenda. Proposed agenda items are subject to change as priorities indicate.

Time will be provided for public comments limited to five minutes each; comments are to be submitted no later than February 15, 2005.

FOR FURTHER INFORMATION CONTACT:

Anyone requiring information regarding the Committee should contact Peter C. van Dyck, M.D., M.P.H., Executive Secretary, ACIM, Health Resources and Services Administration (HRSA), Room 18-05, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, Telephone: (301) 443-2170.

Individuals who are submitting public comments or who have questions regarding the meeting should contact Ann M. Koontz, C.N.M., Dr. P.H., HRSA, Maternal and Child Health Bureau, telephone: (301) 443-6327, e-mail: akoontz@hrsa.gov.

Dated: January 31, 2005.

Steven A. Pelovitz,

Associate Administrator for Administration and Financial Management.

[FR Doc. 05-2102 Filed 2-2-05; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies Federal agencies of the laboratories currently certified to meet the standards of Subpart C of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines). The Mandatory Guidelines were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908), on September 30, 1997 (62 FR 51118), and on April 13, 2004 (69 FR 19644).

A notice listing all currently certified laboratories is published in the **Federal Register** during the first week of each month. If any laboratory's certification is suspended or revoked, the laboratory will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end, and will be omitted from the monthly listing thereafter.

This notice is also available on the Internet at <http://workplace.samhsa.gov> and <http://www.drugfreeworkplace.gov>.

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh or Dr. Walter Vogl, Division of Workplace Programs, SAMHSA/CSAP, Room 2-1035, 1 Choke Cherry Road, Rockville, Maryland 20857; (240) 276-2600 (voice), (240) 276-2610 (fax).

SUPPLEMENTARY INFORMATION: The Mandatory Guidelines were developed in accordance with Executive Order 12564 and section 503 of Pub. L. 100-71. Subpart C of the Mandatory Guidelines, "Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies," sets strict standards that laboratories must meet in order to conduct drug and specimen validity tests on urine specimens for Federal agencies. To become certified, an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection. To maintain that