Research Objectives

(1) Evaluate how mass casualty and disaster situations impact the provision of acute injury care.

(2) Evaluate strategies to translate, disseminate and implement science-based recommendations and guidelines for the care of the acutely injured.

(3) Develop and evaluate new or existing health quality measures to better assess outcomes for persons treated in a pre-hospital or hospital acute injury care setting.

(4) Identify individual, sociocultural and community factors that impact on the immediate and long-term care of the acutely injured.

(5) Develop and evaluate acute injury treatment strategies that will result in evidence-based management for persons who sustain a life-threatening injury or one that could lead to significant disability.

(6) Determine and evaluate the components of pre-hospital and hospital trauma systems that lead to improvements in outcome for the acutely injured.

Infrastructure Objective

(1) Build the acute injury care research infrastructure through the development of an Acute Injury Care Research Network (AICRN).

(2) Determine how existing databases can best be utilized to assess and improve systems of acute injury care.

(3) Develop new training programs and expand and restructure existing training and education for health professionals in injury care, prevention and research.

(4) Determine, evaluate, and address current obstacles in conducting acute injury care research.

Interested persons are invited to comment on the Draft Acute Injury Care Research Agenda. NCIPC will not be able to respond to individual comments, but all comments received by March 3, 2005; will be considered before the final Acute Injury Care Research Agenda is published. A more detailed background document is available upon request. Send requests and comments electronically to *DARDInfo@cdc.gov*.

Dated: January 27, 2005.

James D. Seligman,

Associate Director for Program Services, Centers for Disease Control and Prevention.

[FR Doc. 05–2041 Filed 2–2–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10139]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Center for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR part 1320. This is necessary to ensure compliance with an initiative of the Administration. We cannot reasonably comply with the normal clearance procedures because the normal procedures are likely to cause a statutory deadline to be missed. It is critical to complete the survey and analysis for a Report to Congress due June 2005.

Section 704(C)(2) requires CMS to conduct a study on how non-Medicare/Medicaid Outcome and Assessment Information Set (OASIS) is used by large and small home health agencies (HHA's). The study will investigate whether there are unique benefits from the analysis of such information, the value of collecting such information by small HHA's compared to the administrative burden, a comparison of outcomes for non-Medicare/non-Medicaid patients and Medicare/Medicaid patients, and obtain the opinions of quality assessment experts. The study will consist of a mailed survey of 1200 home health agencies.

CMS is requesting OMB review and approval of this collection by March 7, 2005, with a 180-day approval period. Written comments and recommendation will be accepted from the public if received by the individuals designated below by March 4, 2005.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site address at *http://www.cms.hhs.gov/regulations/pra* or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be mailed and/or faxed to the designees referenced below by March 4, 2005:

Centers for Medicare and Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Room C5–13–27, 7500 Security Boulevard, Baltimore, MD 21244–1850, Fax Number: (410) 786–0262, Attn: William N. Parham, III, CMS–10139 and, OMB Human Resources and Housing Branch, Attention: Christopher Martin, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: January 28, 2005.

John P. Burke, III,

CMS Paperwork Reduction Act Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group.

[FR Doc. 05–2074 Filed 2–2–05; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food and Drug Administration Drug Educational Forum; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

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: ( )

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E-mail: ( )

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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.