

Products—Updating Labeling in RLDs and ANDAs.” The guidance is intended to assist manufacturers of over-the-counter (OTC) reference listed drugs (RLDs) and manufacturers, packers, and distributors of OTC drug products marketed under abbreviated new drug applications (ANDAs) to implement the agency’s regulation on standardized content and format requirements for the labeling of these products.

DATES: The guidance for industry is effective October 18, 2002. Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the guidance to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Gerald M. Rachanow or Cazemiro R. Martin, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2222.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Labeling OTC Human Drug Products—Updating Labeling in RLDs and ANDAs.” This is one of several guidances the agency is developing to help manufacturers, packers, and distributors implement the final regulation establishing standardized content and format requirements for the labeling of all OTC drug products. When finalized, these guidances will supersede all other statements, feedback, and correspondence provided by the agency on these matters since the issuance of the final regulation.

In the **Federal Register** of March 17, 1999 (64 FR 13254), FDA published a final regulation establishing standardized content and format requirements for the labeling of OTC drug products. The regulation is codified at § 201.66 (21 CFR 201.66). It is intended to standardize labeling for all OTC drug products so consumers can

easily read and understand OTC drug product labeling and use these products safely and effectively. The regulation requires manufacturers to present OTC drug product labeling information in a prescribed order and format. This new format will require revision of all existing labeling.

Following issuance of the final regulation, the agency received several inquiries from manufacturers of generic OTC drug products seeking guidance on whether they should convert products to the new labeling format before the manufacturers of the applicable innovator (or RLD) products revise their labeling. To address those inquiries, in the **Federal Register** of February 22, 2001 (66 FR 11174), FDA published a notice announcing the availability of a draft guidance entitled “Labeling Over-the-Counter Human Drug Products; Updating Labeling in ANDAs,” which included draft recommendations about how manufacturers of OTC drug products marketed under ANDAs and manufacturers of the RLD products could implement the agency’s new regulations for the labeling of OTC drug products. The draft guidance contained a series of labeling examples that manufacturers could use when revising their product labeling to the new format. The notice invited interested persons to submit comments on the draft guidance by April 23, 2001.

FDA received several comments regarding the February 22, 2001, draft guidance and, in response, the agency has made some clarifying changes in the final version of the guidance.

Specifically, the agency is providing guidance on its general implementation expectations, the use of agency recommended labeling examples (manufacturers of RLDs who use these do not need agency preapproval), submission of new labeling in an annual report or preapproval supplement, and deferral requests. The agency is also announcing that it intends to exercise its enforcement discretion by giving manufacturers of generic OTC drug products a grace period to comply with the new format requirements of § 201.66. This grace period commenced on May 16, 2002, for most OTC ANDAs and shall continue until the agency posts on the Internet the approved, updated labeling for an ANDA holder’s applicable RLD. At that time, the ANDA holder should revise its labeling. (See the agency’s May 2000 guidance for industry entitled “Revising ANDA Labeling Following Revision of the RLD Labeling.”)

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115).

The guidance represents the agency’s current thinking on updating labeling in ANDAs consistent with the new standardized labeling content and format required for OTC drug products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such an approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may, at any time, submit written or electronic comments on the guidance to the Dockets Management Branch (see **ADDRESSES**). Two 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. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/cder/guidance/index.htm> and <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: October 10, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02-26622 Filed 10-17-02; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Health Professions and Nurse Education Special Emphasis Panel; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following Health Professions and Nurse Education Special Emphasis Panel meetings. Part of the meeting will be open to the public. The rest of the meeting will be closed to the public. The closing is in accordance with the provision set forth in section 552(b)(3)(C), Title 5 U.S.C., and the Determination by the Associate Administrator for Management and Program Support, Health Resources and Services Administration, pursuant to Public Law 92-463.

Name: Dental Public Health.

Date and Time: November 18–21, 2002.
Place: Hilton Silver Spring, 8727 Colesville Road, Silver Spring, MD 20910.

Open on: November 18, 2002, 8 a.m. to 10 a.m.

Closed on: November 18, 2002, 10 a.m. to 6 p.m., November 19–21, 2002, 8 a.m. to 6 p.m.

Name: Residency Training in Primary Care.

Date and Time: December 2–5, 2002.

Place: Hilton Silver Spring, 8727 Colesville Road, Silver Spring, MD 20910.

Open on: December 2, 2002, 8 a.m. to 10 a.m.

Closed on: December 2, 2002, 10 a.m. to 6 p.m., December 3–5, 2002, 8 a.m. to 6 p.m.

Name: Residency Training in Primary Care.

Date and Time: December 9–12, 2002.

Place: Hilton Silver Spring, 8727 Colesville Road, Silver Spring, MD 20910.

Open on: December 9, 2002, 8 a.m. to 10 a.m.

Closed on: December 9, 2002, 10 a.m. to 6 p.m., December 10–12, 2002, 8 a.m. to 6 p.m.

Name: Residency Training in General and Pediatric Dentistry.

Date and Time: December 16–19, 2002.

Place: Hilton Silver Spring, 8727 Colesville Road, Silver Spring, MD 20910.

Open on: December 16, 2002, 8 a.m. to 10 a.m.

Closed on: December 16, 2002, 10 a.m. to 6 p.m., December 17–19, 2002, 8 a.m. to 6 p.m.

Name: Predoctoral Training in Primary Care.

Date and Time: January 13–16, 2003.

Place: Hilton Silver Spring, 8727 Colesville Road, Silver Spring, MD 20910.

Open on: January 13, 2003, 8 a.m. to 10 a.m.

Closed on: January 13, 2003, 10 a.m. to 6 p.m., January 14–16, 2003, 8 a.m. to 6 p.m.

Name: Faculty Development Training in Primary Care.

Date and Time: January 21–24, 2003.

Place: Hilton Silver Spring, 8727 Colesville Road, Silver Spring, MD 20910.

Open on: January 21, 2003, 8 a.m. to 10 a.m.

Closed on: January 21, 2003, 10 a.m. to 6 p.m., January 22–24, 2003, 8 a.m. to 6 p.m.

Name: Physician Assistant Training in Primary Care.

Date and Time: January 27–30, 2003.

Place: Hilton Silver Spring, 8727 Colesville Road, Silver Spring, MD 20910.

Open on: January 27, 2003, 8 a.m. to 10 a.m.

Closed on: January 27, 2003, 10 a.m. to 6 p.m., January 28–30, 2003, 8 a.m. to 6 p.m.

Name: Nursing Workforce Diversity.

Date and Time: February 3–6, 2003.

Place: Hilton Silver Spring, 8727 Colesville Road, Silver Spring, MD 20910.

Open on: February 3, 2003, 8 a.m. to 10 a.m.

Closed on: February 3, 2003, 10 a.m. to 6 p.m., February 4–6, 2003, 8 a.m. to 6 p.m.

Name: Model State-Supported Area Health Education Centers.

Date and Time: February 10–13, 2003.

Place: Hilton Silver Spring, 8727 Colesville Road, Silver Spring, MD 20910.

Open on: February 10, 2003, 8 a.m. to 10 a.m.

Closed on: February 10, 2003, 10 a.m. to 6 p.m., February 11–13, 2003, 8 a.m. to 6 p.m.

Name: Basic/Core Area Health Education Centers.

Date and Time: February 10–13, 2003.

Place: Hilton Silver Spring, 8727 Colesville Road, Silver Spring, MD 20910.

Open on: February 10, 2003, 8 a.m. to 10 a.m.

Closed on: February 10, 2003, 10 a.m. to 6 p.m., February 11–13, 2003, 8 a.m. to 6 p.m.

Name: Geriatric Faculty Fellowships.

Date and Time: February 10–13, 2003.

Place: Hilton Silver Spring, 8727 Colesville Road, Silver Spring, MD 20910.

Open on: February 10, 2003, 8 a.m. to 10 a.m.

Closed on: February 10, 2003, 10 a.m. to 6 p.m., February 11–13, 2003, 8 a.m. to 6 p.m.

Name: Academic Administrative Units in Primary Care.

Date and Time: February 24–27, 2003.

Place: Hilton Silver Spring, 8727 Colesville Road, Silver Spring, MD 20910.

Open on: February 24, 2003, 8 a.m. to 10 a.m.

Closed on: February 24, 2003, 10 a.m. to 6 p.m., February 25–27, 2003, 8 a.m. to 6 p.m.

Name: Quentin N. Burdick Program for Rural Interdisciplinary Training.

Date and Time: February 24–28, 2003.

Place: Hilton Silver Spring, 8727 Colesville Road, Silver Spring, MD 20910.

Open on: February 24, 2003, 8 a.m. to 10 a.m.

Closed on: February 24, 2003, 10 a.m. to 6 p.m., February 25–28, 2003, 8 a.m. to 6 p.m.

Name: Advanced Education Nursing.

Date and Time: March 3–6, 2003.

Place: Hilton Silver Spring, 8727 Colesville Road, Silver Spring, MD 20910.

Open on: March 3, 2003, 8 a.m. to 10 a.m.

Closed on: March 3, 2003, 10 a.m. to 6 p.m., March 4–6, 2003, 8 a.m. to 6 p.m.

Name: Regional Workforce Centers.

Date and Time: March 3–6, 2003.

Place: Hilton Silver Spring, 8727 Colesville Road, Silver Spring, MD 20910.

Open on: March 3, 2003, 8 a.m. to 10 a.m.

Closed on: March 3, 2003, 10 a.m. to 6 p.m., March 4–6, 2003, 8 a.m. to 6 p.m.

Name: Advanced Education Nursing.

Date and Time: March 10–13, 2003.

Place: Hilton Silver Spring, 8727 Colesville Road, Silver Spring, MD 20910.

Open on: March 10, 2003, 8 a.m. to 10 a.m.

Closed on: March 10, 2003, 10 a.m. to 6 p.m., March 11–13, 2003, 8 a.m. to 6 p.m.

Name: Basic Nurse Education and Practice Grants Program, Peer Review Group I.

Date and Time: March 17–20, 2003.

Place: Hilton Silver Spring, 8727 Colesville Road, Silver Spring, MD 20910.

Open on: March 17, 2003, 8 a.m. to 10 a.m.

Closed on: March 17, 2003, 10 a.m. to 6 p.m., March 18–20, 2003, 8 a.m. to 6 p.m.

Name: Geriatric Education Centers.

Date and Time: March 24–27, 2003.

Place: Hilton Silver Spring, 8727 Colesville Road, Silver Spring, MD 20910.

Open on: March 24, 2003, 8 a.m. to 10 a.m.

Closed on: March 24, 2003, 10 a.m. to 6 p.m., March 25–27, 2003, 8 a.m. to 6 p.m.

Name: Basic Nurse Education and Practice Grants Program, Peer Review Group II.

Date and Time: March 31–April 3, 2003.

Place: Hilton Silver Spring, 8727 Colesville Road, Silver Spring, MD 20910.

Open on: March 31, 2003, 8 a.m. to 10 a.m.

Closed on: March 31, 2003, 10 a.m. to 6 p.m., April 1–3, 2003, 8 a.m. to 6 p.m.

Name: Allied Health Projects.

Date and Time: April 7–11, 2003.

Place: Hilton Silver Spring, 8727 Colesville Road Avenue, Silver Spring, MD 20910.

Open on: April 7, 2003, 8 a.m. to 10 a.m.

Closed on: April 7, 2003, 10 a.m. to 6 p.m., April 8–11, 2002, 8 a.m. to 6 p.m.

Name: Centers of Excellence.

Date and Time: April 7–11, 2003.

Place: Hilton Silver Spring, 8727 Colesville Road Avenue, Silver Spring, MD 20910.

Open on: April 7, 2003, 8 a.m. to 10 a.m.

Closed on: April 7, 2003, 10 a.m. to 6 p.m., April 8–11, 2002, 8 a.m. to 6 p.m.

Name: Health Careers Opportunity Program Peer Review Group.

Date and Time: May 5–9, 2003.

Place: Hilton Silver Spring, 8727 Colesville Road, Silver Spring, MD 20910.

Open on: May 5, 2003, 8 a.m. to 10 a.m.

Closed on: May 5, 2003, 10 a.m. to 6 p.m., May 6–9, 2003, 8 a.m. to 6 p.m.

Name: Geriatric Academic Career Awards.

Date and Time: May 12–15, 2003.

Place: Hilton Silver Spring, 8727 Colesville Road, Silver Spring, MD 20910.

Open on: May 12, 2003, 8 a.m. to 10 a.m.

Closed on: May 12, 2003, 10 a.m. to 6 p.m., May 13–15, 2003, 8 a.m. to 6 p.m.

Name: Public Health Training Centers.

Date and Time: May 19–22, 2003.

Place: Hilton Silver Spring, 8727 Colesville Road, Silver Spring, MD 20910.

Open on: May 19, 2003, 8 a.m. to 10 a.m.

Closed on: May 19, 2003, 10 a.m. to 6 p.m., May 20–22, 2003, 8 a.m. to 6 p.m.

Name: Chiropractic Demonstration Project.

Date and Time: June 9–12, 2003.

Place: Hilton Silver Spring, 8727 Colesville Road, Silver Spring, MD 20910.

Open on: June 9, 2003, 8 a.m. to 10 a.m.

Closed on: June 9, 2003, 10 a.m. to 6 p.m., June 10–12, 2003, 8 a.m. to 6 p.m.

Purpose: The Health Professions and Nurse Education Special Emphasis Panel shall advise the Associate Administrator for Health Professions on the technical merit of grants to improve the training, distribution, utilization, and quality of personnel required to staff the Nation's health care delivery system.

Agenda: The open portion of each meeting from 8 a.m. to approximately 10 a.m. will cover introductions, opening remarks, housekeeping details, and an orientation to the review process. The meetings will be closed at approximately 10:00 a.m. on the first day of each meeting until adjournment for the review of grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

For Further Information Contact: Anyone wishing to obtain a roster of members or other relevant information should write or contact Ms. Wilma Johnson, Acting Deputy Director, Office of Peer Review, Bureau of

Health Professions, Parklawn Building, Room 8C-23, 5600 Fishers Lane, Rockville, Maryland 20857, telephone 301-443-6339.

Dated: October 11, 2002.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 02-26623 Filed 10-17-02; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4734-N-60]

Notice of Submission of Proposed Information Collection to OMB: Survey of Neighborhood Networks Centers Directors

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* November 18, 2002.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval number and should be sent to: Lauren Wittenberg, OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503; Fax number (202) 395-6974; e-mail Lauren_Wittenberg@omb.eop.gov.

FOR FURTHER INFORMATION CONTACT:

Wayne Eddins, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 Seventh Street, Southwest, Washington, DC 20410; e-mail Wayne_Eddins@HUD.gov; telephone (202) 708-2374. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35). The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the

information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the name and telephone number of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

This Notice also lists the following information:

Title of Proposal: Survey of Neighborhood Networks Centers Directors.

OMB Approval Number: 2502-XXXX.

Form Numbers: None.

Description of the Need for the Information and its Proposed Use: A Survey of Neighborhood Networks Centers will identify successful program areas, and target specific areas for improvement.

Respondents: Business or other for-profit, not-for profit institutions.

Frequency of Submission: Annually.

	Number of respondents	×	Annual responses	×	Hours per response	=	Burden hours
Reporting Burden	800		1		0.9		733

Total Estimated Burden Hours: 733.
Status: New collection.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: October 10, 2002.

Wayne Eddins,

*Departmental Reports Management Officer,
Office of the Chief Information Officer.*

[FR Doc. 02-26485 Filed 10-17-02; 8:45 am]

BILLING CODE 4210-72-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Federal Property Suitable as Facilities To Assist the Homeless

[Docket No. FR-4730-N-42]

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and

surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

FOR FURTHER INFORMATION CONTACT:

Mark Johnston, room 7266, Department of Housing and Urban Development, 451 Seventh Street SW, Washington, DC 20410; telephone (202) 708-1234; TTY number for the hearing- and speech-impaired (202) 708-2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line a 1-800-927-7588.

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding

its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless v. Veterans Administration*, No. 88-2503-OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days