requirements can be converted to the new format.

DATES: Submit written or electronic comments on the draft guidance for industry by March 14, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Cazemiro R. Martin or Gerald M. Rachanow, 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FDA is announcing the availability of a draft guidance for industry entitled ''Labeling OTC Human Drug Products—Questions and Answers.'' This is one of several draft guidances the agency is developing to help manufacturers, packers, and distributors implement the regulation establishing standardized content and format requirements for the labeling of all OTC drug products. Once finalized, these draft guidances will supersede all other statements, feedback, and correspondence provided by the agency on these matters since the issuance of the final rule.

In the **Federal Register** of March 17, 1999 (64 FR 13254), FDA published a final rule establishing standardized content and format requirements for the labeling of OTC drug products (21 CFR 201.66). This regulation 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 for this standardized labeling requires manufacturers to present OTC drug labeling information in a prescribed order and format. The standardized format will require revision of all labeling in use before the compliance date of the final rule. The final rule covers all OTC drug and drug-cosmetic products, whether marketed under a new drug marketing application, abbreviated new drug application, or OTC drug monograph (or product not yet the subject of a final OTC drug monograph).

Following issuance of the final rule, the agency received a number of inquires from manufacturers seeking guidance on how to present the labeling information for their OTC drug products using the standardized content and format requirements. This draft guidance discusses those inquiries and provides labeling examples to show various format and content features of the labeling requirements and suggest how OTC drug monograph labeling finalized before the new regulation was issued can be converted to the new format. This draft guidance also discusses how to list inactive ingredients that may or may not be contained in the OTC drug product.

This level I draft guidance is being issued consistent with FDA's good guidance practices (21 CFR 10.115). The draft guidance includes labeling examples that are consistent with the new OTC drug products standardized labeling content and format. The draft guidance represents the agency's current thinking on how OTC drug monograph labeling can be converted to the new OTC ''Drug Facts'' format labeling. 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 submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Submit a single copy of electronic comments or two copies of any mailed comments except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management 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 either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: December 28, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 05–696 Filed 1–12–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Surveys of Safety Net Providers for the Healthy Communities Access Program National Evaluation—New

The Bureau of Primary Health Care, Health Resources and Services Administration, is conducting a national evaluation of the Healthy Communities Access Program (HCAP) as required by section 340(i) of the Public Health Service Act (42 U.S.C. 256) Public Law 107–251, Oct. 26, 2002.

Surveys of Safety Net Providers and Consortium Leaders will be performed to provide essential information not otherwise available for the national evaluation. Based on consortia response rates of 70% for the provider survey and 75% for the consortia leader survey, it is estimated that 405 Safety Net Providers and 145 Consortia Leaders will complete the surveys.

A preliminary review of the sampling frame for safety net providers indicates that the allocated sample provides adequate representation of all provider types of interest. Legislatively required provider members of HCAP consortia are included in the sample, *i.e.*, hospitals, federally qualified health centers, public health departments, and public/private providers that serve the medically underinsured and underserved. The survey results will be considered along with information from other quantitative and qualitative data

sources (including national, State and local data and information from grantee consortia leaders and clients) in order to develop a Report to Congress in September 2005 and a national evaluation report by September 2006. The survey will collect data for key evaluation goals including coordination and integration of safety net services, capacity and access issues, health care delivery, quality of care, cost savings, sustainability, and provider and patient satisfaction.

The survey of the HCAP consortia leaders, who typically are project directors, is a short Web-based survey of 12 questions that will be available through the HRSA HCAP Web site. The sample of eligible consortia includes all those who have received HCAP funding, with the exception of the most recent round of HCAP grantees. These grantees were excluded from the sample because they lack program experience that would provide the evaluation with significant information. This survey will be used to assess consortia leaders' perspectives on the strengths and limitations of using consortia to strengthen the community safety net. It will query leaders on the perceived efficacy of the consortia approach, accomplishments, strengths, weaknesses and suggestions/areas for future improvement of the program. The burden estimate is as follows:

Data collection	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Provider Survey	405	1	405	.33	134
Consortia Leaders Survey	145	1	145	.25	36
Totals	550		550		170

Request for Comments: Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Desk Officer, Health Resources and Services Administration, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: January 7, 2005.

Steven A. Pelovitz,

Associate Administrator for Administration and Financial Management.

[FR Doc. 05–671 Filed 1–12–05; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Interdisciplinary, Community-Based Linkages; 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 Interdisciplinary, Community-Based Linkages.

Dates and Times: January 31, 2005, 8:30 a.m.–5 p.m. February 1, 2005, 8:30 a.m.–5 p.m. February 2, 2005, 8:30 a.m.–2 p.m.

Place: The DoubleTree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Status: The meeting will be open to the public.

Agenda: Agenda items will include, but not be limited to: Welcome; plenary session on Allied Health issues as they relate to the grant programs under the purview of the Committee with presentations by speakers representing the Department of Health and Human Services (DHHS), constituent groups, field experts and committee members. The following topics will be addressed at the meeting: What are HRSA/BHPr's Allied Health projects and what does the legislation dictate; what is the past history, current status, and future outlook of Allied Health; and, what is the Allied Health Reinvestment Act (S. 2491/H.R. 4016—108th Congress).

Proposed agenda items are subject to change as priorities dictate.

Public Comments: Public comment will be permitted at the end of the Committee meeting on January 31, 2005, and before lunch on February 1, 2005. Oral presentations will be limited to 5 minutes per public speaker. Persons interested in providing an oral presentation should submit a written request, with a copy of their presentation to: Ann Bell, Public Health Fellow, Division of State, Community and Public Health, Bureau of Health Professions, Health Resources and Services Administration, Room 8A–09, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–0582.

Requests should contain the name, address, telephone number, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The Division of State, Community and Public Health will notify each presenter by mail or telephone of their assigned presentation time.

Persons who do not file a request in advance for a presentation, but wish to make an oral statement may register to do so at the DoubleTree Hotel, Rockville, MD, on January 31, 2005. These persons will be allocated time as the Committee meeting agenda permits.

For Further Information Contact: Anyone requiring information regarding the Committee should contact Ann Bell, Division of State, Community and Public Health, Bureau of Health Professions, Health Resources and Services Administration, Room 8A–09, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–0582.

Dated: January 7, 2005.

Steven A. Pelovitz,

Associate Administrator for Administration and Financial Management.

[FR Doc. 05–670 Filed 1–12–05; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Request for Nominations of Members To Serve on the Bureau of Indian Affairs Advisory Board for Exceptional Education

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of request for nominations.

SUMMARY: Pursuant to the Federal Advisory Committee Act (FACA) and the Individuals with Disabilities Education Act (IDEA), the Bureau of Indian Affairs (BIA), Office of Indian Education Programs (OIEP), requests nominations of individuals to serve on the BIA Advisory Board for Exceptional Education (Advisory Board). The BIA/OIEP will consider nominations received in response to this Request for Nominations. The **SUPPLEMENTARY INFORMATION** section provides committee and membership criteria, and the membership nomination form.

DATES: Submit nominations on or before February 14, 2005.

ADDRESSES: Please submit nomination applications to Gloria Yepa, Supervisory Education Specialist, BIA, OIEP, Center For School Improvement, 500 Gold