submissions may be made to the contact person by January 6, 2005. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 9:30 a.m. on January 14, 2005. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 6, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact LaNise Giles at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 1, 2004.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 04–26995 Filed 12–8–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0327]

Draft Compliance Guidance for Small Business Entities on Labeling Over-the-Counter Human Drug Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft compliance guidance for small business entities entitled ''Labeling OTC Human Drug Products; Small Entity Compliance Guide.'' FDA has prepared this guidance in accordance with the Small Business Regulatory Enforcement Fairness Act. It is intended to help small businesses better understand the new over-the-counter (OTC) labeling requirements and to prepare new labeling within the prescribed implementation compliance dates.

DATES: Submit written or electronic comments on the draft compliance guidance by February 7, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft compliance 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 compliance 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 compliance 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: FDA is announcing the availability of a draft compliance guidance for small business entities entitled ''Labeling OTC Human Drug Products; Small Entity Compliance Guide.'' FDA has prepared this guidance in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act. This is one of several guidances the agency is developing to help manufacturers, packers, and distributors implement the final rule establishing standardized content and format requirements for the labeling of all OTC drug products. Once finalized, these 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 regulations for the labeling of OTC drug products. 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 new standardized labeling requires manufacturers to present OTC drug labeling information in a prescribed order and format. The new format will require revision of all existing labeling and covers all OTC drug and drug-cosmetic products, whether marketed under a new drug marketing application (NDA), abbreviated new drug application (ANDA), or OTC drug monograph (or product not yet the subject of a final OTC drug monograph). To reduce the economic impact on small business entities, the new regulations provide an additional 1-year period to comply with § 201.66 (21 CFR 201.66) for OTC drug products with sales of less than $25,000 per year. You can find a copy of § 201.66 at the Division of Dockets Management Web site at *http://www.fda.gov/cder/otc/label/label-fr-reg.htm*.

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 new standardized content and format requirements. This draft guidance summarizes the new Drug Facts labeling requirements as set forth in § 201.66. The draft guidance also describes how to list those inactive ingredients that are different when a finished OTC drug product is obtained from multiple suppliers.

This draft guidance is being issued consistent with FDA's good guidance practices (21 CFR 10.115). The draft compliance guidance, when finalized, will represent the agency's current thinking on how OTC drug monograph labeling finalized prior to or after the new requirements 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 approach satisfies the requirements of the applicable statutes and regulations.

I. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft compliance guidance. Two copies of mailed 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 draft compliance 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.

II. 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 1, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–26993 Filed 12–8–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4903–N–98]

Notice of Submission of Proposed Information Collection to OMB; Resident Services and Satisfaction Survey

AGENCY: Office of the Chief Information Officer.

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.

This is a request for continued approval to collect the information related to a survey of residents of assisted housing and insured housing. HUD conducts this to measure resident satisfaction with living conditions. Public housing agencies are required to implement the survey.

DATES: Comments Due Date: January 10, 2005.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval Number (2507–0001) and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, AYO, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; e-mail *Wayne_Eddins@HUD.gov;* or Lillian Deitzer at *Lillian_L_Deitzer@HUD.gov* or telephone (202) 708–2374. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Mr. Eddins or Ms. Deitzer and at HUD's Web site at *http://www5.hud.gov:63001/po/i/icbts/collectionsearch.cfm.*

SUPPLEMENTARY INFORMATION: This Notice informs the public that the U.S. Department of Housing and Urban Development (HUD) has submitted to OMB a request for approval of the information collection described below. This Notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Resident Service and Satisfaction Survey.

OMB Approval Number: 2507–0001.

Form Numbers: None.

Description of the Need for the Information and Its Proposed Use: HUD conducts a resident survey of assisted and insured housing residents to measure resident satisfaction with living conditions. Public housing agencies are required to implement the survey.

Frequency of Submission: Annually.

	Potential respondents	Annual responses	x	Hours per response	=	Burden hours
Reporting Burden	595,797	216,979		0.3		64,021

The total potential respondents include public housing agencies, multifamily housing owners, and residents.

Total Estimated Burden Hours: 64,021.

Status: Extension of a currently approved collection.

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

Dated: December 2, 2004.

Wayne Eddins,

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

[FR Doc. E4–3560 Filed 12–8–04; 8:45 am]

BILLING CODE 4210–72–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4837–D–54]

Delegation of Authority Under Section 42(d)(5)(C) of the Internal Revenue Code

AGENCY: Office of the Secretary, HUD.

ACTION: Notice.

SUMMARY: In this notice, the Secretary delegates to the Assistant Secretary for Policy Development and Research concurrent authority to carry out the duties and responsibilities authorized to the Secretary of HUD by Section 42(d)(5)(C) of the Internal Revenue Code.

DATES: *Effective Date:* January 1, 2005.

FOR FURTHER INFORMATION CONTACT: Kurt G. Usowski, Associate Deputy Assistant Secretary for Economic Affairs, Office of Policy Development and Research, Room 8204, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410–6000, telephone (202) 708–2770 (this is not a toll-free number), or email *Kurt_G._Usowski@hud.gov.* Persons with speech or hearing impairments may access this number through TTY by calling the Federal Information Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION: Section 42(d)(5)(C) of the Internal Revenue Code of 1986 (26 U.S.C. 42(d)(5)(C)) authorizes the Secretary of HUD to designate qualified census tracts and difficult development areas for the low-income housing tax credit. Section 7(d) of the Department of Housing and Urban Development Act (42 U.S.C. 3535(d)) authorizes the Secretary to delegate this authority, and the Secretary delegates the authority as follows: