

any relatives. An unrelated individual may be the only person living in a house or apartment, or may be living in a house or apartment (or in group quarters such as a rooming house) in which one or more persons also live who are not related to the individual in question by birth, marriage, or adoption. Examples of unrelated individuals residing with others include a lodger, a foster child, a ward, or an employee.

(c) **Household.** As defined by the Bureau of the Census for statistical purposes, a household consists of all the persons who occupy a housing unit (house or apartment), whether they are related to each other or not. If a family and an unrelated individual, or two unrelated individuals, are living in the same housing unit, they would constitute two family units (see next item), but only one household. Some programs, such as the Food Stamp Program and the Low-Income Home Energy Assistance Program, employ administrative variations of the "household" concept in determining income eligibility. A number of other programs use administrative variations of the "family" concept in determining income eligibility. Depending on the precise program definition used, programs using a "family" concept would generally apply the poverty guidelines separately to each family and/or unrelated individual within a household if the household includes more than one family and/or unrelated individual.

(d) **Family Unit.** "Family unit" is not an official U.S. Bureau of the Census term, although it has been used in the poverty guidelines **Federal Register** notice since 1978. As used here, either an unrelated individual or a family (as defined above) constitutes a family unit. In other words, a family unit of size one is an unrelated individual, while a family unit of two/three/etc. is the same as a family of two/three/etc.

Note that this notice no longer provides a definition of "income." This is for two reasons. First, there is no universal administrative definition of "income" that is valid for all programs that use the poverty guidelines. Second, in the past there has been confusion regarding important differences between the statistical definition of income and various administrative definitions of "income" or "countable income." The precise definition of "income" for a particular program is very sensitive to the specific needs and purposes of that program. To determine, for example, whether or not taxes, college scholarships, or other particular types of income should be counted as "income" in determining eligibility for a specific

program, one must consult the office or organization administering the program in question; that office or organization has the responsibility for making decisions about the definition of "income" used by the program (to the extent that the definition is not already contained in legislation or regulations).

Dated: February 9, 2000.

Donna E. Shalala,

Secretary of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

CDC Advisory Committee on HIV and STD Prevention: Meeting.

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

NAME: CDC Advisory Committee on HIV and STD Prevention.

TIME AND DATE: 3 p.m.-4:30 p.m., February 28, 2000.

PLACE: Teleconference Call

Telephone Bridge Number for Federal Participants: 404-639-4100.

Conference Telephone Bridge Number for Non-Federal Participants: 1-800-713-1971.

Conference Code: 293470.

STATUS: Open to the public, limited only by the space available. The teleconference will accommodate approximately 100 people.

PURPOSE: This Committee is charged with advising the Director, CDC, regarding objectives, strategies, and priorities for HIV and STD prevention efforts including maintaining surveillance of HIV infection, AIDS, and STDs, the epidemiologic and laboratory study of HIV/AIDS and STDs, information/education and risk reduction activities designed to prevent the spread of HIV and STDs, and other preventive measures that become available.

MATTERS TO BE DISCUSSED: Agenda items include a discussion of recommendations pertaining to evolving HIV prevention priorities related to programs, surveillance and research.

CONTACT PERSON FOR MORE INFORMATION: Paulette Ford, Committee Management Analyst, National Center for HIV, STD, and TB Prevention, 1600 Clifton Road, NE, M/S E-07, Atlanta, Georgia 30333.

Telephone 404/639-8008, fax 404/639-8600, e-mail pbf7@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register Notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: February 10, 2000.

John Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 00-3611 Filed 2-14-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-0218]

Draft "Guidance for Reviewers: Potency Limits for Standardized Dust Mite and Grass Allergen Vaccines: A Revised Protocol;" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Reviewers: Potency Limits for Standardized Dust Mite and Grass Allergen Vaccines: A Revised Protocol" dated January, 2000. The draft guidance document provides information on the revised release limits to be used by the Center for Biologics Evaluation and Research (CBER) for its evaluation of standardized dust mite and grass allergen vaccines submitted to CBER for lot release. The establishment of suitable potency limits for standardized allergen vaccines submitted to CBER for lot release helps to ensure the safety, purity, and potency of these products.

DATES: Written comments may be submitted at any time, however, comments should be submitted by May 15, 2000, to ensure their adequate consideration in preparation of the final document.

ADDRESSES: Submit written requests for single copies of "Guidance for Reviewers: Potency Limits for Standardized Dust Mite and Grass Allergen Vaccines: A Revised Protocol" dated January, 2000 to the Office of Communication, Training, and Manufacturers Assistance (HFM-40),

Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800, or by fax by calling the FAX Information System at 1-888-CBER-FAX or 301-827-3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the document to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Joseph L. Okrasinski, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled "Guidance for Reviewers: Potency Limits for Standardized Dust Mite and Grass Allergen Vaccines: A Revised Protocol" dated January, 2000. The draft guidance document, when finalized, would provide information to FDA reviewers regarding broader relative potency limits for CBER evaluation of standardized dust mite and grass allergen vaccines submitted to CBER for lot release. Issues addressed in the guidance document, include but are not limited to, the following: (1) Diagnostic Equivalence, (2) therapeutic equivalence, (3) safety equivalence, (4) lot-to-lot variation in allergen vaccine potency, and (5) current and broadened CBER release limits for standardized dust mite and grass allergen vaccines submitted to CBER for lot release.

This draft guidance document represents the agency's current thinking with regard to the potency limits for standardized dust mite and grass allergen vaccines. 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 requirement of the applicable statute, regulations, or both. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

This draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document. Submit Written comments at any time, however, comments should be submitted by May 15, 2000, to ensure adequate consideration in preparation of the final document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document 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/cber/guidelines.htm>.

Dated: February 8, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects

(section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443-1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Grants for Hospital Construction and Modernization—Federal Right of Recovery and Waiver of Recovery (42 CFR, Subpart H) (OMB No. 0915-0099)—Extension

The regulation known as "Federal Right of Recovery and Waiver of Recovery," provides a means for the Federal Government to recover grant funds and a method of calculating interest when a grant-assisted facility under Title VI and XVI is sold or leased, or there is a change in use of the facility. It also allows for a waiver of the right of recovery under certain circumstances. Facilities are required to provide written notice to the Federal Government when such a change occurs; and to provide copies of sales contracts, lease agreements, estimates of current assets and liabilities, value of equipment, expected value of land on the new owner's books and remaining depreciation for all fixed assets involved in the transactions, and other information and documents pertinent to the change of status.

ESTIMATES OF ANNUALIZED HOUR BURDEN

Regulation	Number of respondents	Responses per respondent	Hours per response	Total burden hours
124.704(b) and 707	20	1	3	60