

annual report. As a result of the public comments and editorial changes, the guidance is clearer and more concise than the draft version. Furthermore, the scope of the guidance has been changed to exclude proteins and biologics. The agency is considering developing a separate guidance on INDs for these types of drugs.

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in this guidance were approved under OMB Control No. 0910–0014.

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 CMC content and format of INDs for phase 2 and 3 studies of certain drugs. 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.

II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the guidance. Submit a single copy of electronic comments or two paper 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 guidance and received comments may be seen 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 either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

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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 the 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 at (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: Ryan White Comprehensive AIDS Resources Emergency (CARE) Act and Minority AIDS Initiative (MAI) Survey: New

The purpose of the Ryan White CARE Act is to provide emergency assistance to localities that are disproportionately affected by the human immunodeficiency virus (HIV) epidemic and to make financial assistance available for the development, organization, coordination, and operation of more effective and cost-efficient systems for the delivery of essential services to persons with HIV disease. The CARE Act also provides grants to States, eligible metropolitan areas, community-based programs, and early intervention programs for the delivery of services to individuals and families with HIV infection.

The HRSA's HIV/AIDS Bureau (HAB) administers Titles I, II, III, and IV of the Ryan White CARE Act of 1990, as amended by the Ryan White CARE Act

Amendments of 1996 and 2000 (codified under Title XXVI of the Public Health Service Act).

In 1998, President Clinton declared that HIV was a severe and ongoing health crisis among racial/ethnic minority communities. In response to the President's declaration, in fiscal year 1999 the Congressional Black Caucus (CBC) announced funding of a new initiative to address the disproportionate impact of HIV on African-American and Hispanic communities. Since 1999, the initial CBC initiative has been broadened to address the HIV epidemic in other racial and ethnic minority communities. Currently, the HRSA, the Centers for Disease Control and Prevention, the National Institutes of Health, the Office of Public Health and Sciences' Office of Minority Health, the Indian Health Service, and the Substance Abuse and Mental Health Services Administration allocate MAI funds. Direct service providers receiving MAI funds through HAB include organizations whose board of directors and/or direct service employees are racial/ethnic minorities, as well as organizations whose mission is focused on providing care to racial/ethnic minority populations.

The Fax Consultation Form for Minority Providers and Providers Receiving MAI Funds is designed to collect information from (1) service providers receiving MAI funds and (2) service providers funded by the Ryan White CARE Act whose board members or direct service staff are predominantly racial/ethnic minority members.

The Fax Consultation Form will address several over-arching questions including: (1) Have the MAI funds increased the number of persons served and the type and availability of services provided in communities of color; (2) have the MAI funds increased the capacity of minority and other CARE Act service providers to provide care and services in communities of color; (3) what has been the impact of MAI funded training, technical assistance (TA), and capacity building of minority and other organizations; and (4) what administrative impact have MAI funds had on CARE Act programs? Information obtained from the Fax Consultation Form for Minority Providers and Providers Receiving MAI Funds will be used to address the over-arching questions, plan new technical assistance and capacity development activities, and inform HAB policies and program management.

The Fax Consultation Form for Minority Providers and Providers Receiving MAI Funds will be transmitted by facsimile to service