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. Send comments to Anne O'Connor, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project: Adolescents At Risk for HIV: Planning for a Community-Level Intervention—New—National Center for HIV, STD, and TB Prevention (NCHSTP), Centers for Disease Control and Prevention (CDC). The purpose of this request is to obtain approval to conduct a formative research study to understand the prevalence of HIV prevention and drug use behaviors and their influences among adolescent children of women who use crack. Adolescent children of parents who use crack experience a range of individual and environmental risk factors that increase their susceptibility to HIV due to their parents' drug and sexual risk behaviors and resource-poor environments. Despite the multiple risk factors, these adolescents often do not receive community-level HIV prevention services that promote their healthy development into young adults.

The goals of the study are to identify individual, parent, peer, school, and community influences on HIV prevention and risk behaviors of adolescent children of crack users in an urban North Carolina community and to develop a community-level HIV prevention intervention plan targeting these adolescents. The objectives of the study are to (a) conduct adolescent interviews and observations of their neighborhoods; (b) to conduct maternal interviews; (c) to administer mailed teacher questionnaires; and (d) to interview community providers.

The sample will be drawn from mothers participating in an HIV prevention intervention tailored to African-American women reporting current crack use. To be eligible for the proposed study, women must (1) be mothers; (b) report that they have at least one child between 12 and 17 years old who is currently living in the same household; (c) provide written consent for their adolescent child(ren) to participate in this study; and (d) provide written consent to gather information from their child(ren)'s teacher about his/her behavior and school performance. Mothers will be asked about their drug use and risk behaviors, parenting, and their adolescents' behaviors and school performance. Adolescents will be asked about their current drug use, abstinence and/or sexual experience, behaviors, school performance, HIV/AIDS-related beliefs, and other perceived influences from family, school, and peers. During individual interviews, adolescent participants will be asked for the name of the teacher with whom they spend the most time at school. These teachers will be invited to complete a mailed questionnaire about the target adolescents' behavior and school performance, as well as a brief survey about school-level HIV prevention resources and barriers, and perceptions of student substance abuse and health behaviors. Maternal, adolescent, and teacher questions will be drawn from the Achenbach behavior rating system and other youth surveys (e.g., the National Household Survey on Drug Abuse) with national comparison data. Community providers from local organizations that provide formal and informal services to adolescents will be interviewed to assess current services, resources, utilization, accessibility, and barriers to care. Community observations will also be conducted in settings identified by adolescents as places and neighborhoods they frequent to identify geographic information that may serve to mobilize community resources toward an HIV prevention intervention.

The data will be summarized to understand the prevalence of HIV prevention and drug use behaviors and their influences within the study sample of adolescent children of mothers who use crack. Together, these data will be presented at a planning meeting with key community providers near the close of the study. The purpose of this meeting will be to facilitate community-level collaboration and to develop a community intervention plan to prevent HIV among high-risk adolescent children of crack users.

There is no cost to respondents.

Respondents	Number of respondents	Number of responses per respondent	Average response/burden (in hours)	Total burden (in hours)
Mothers	154	1	75/60	192.5
Adolescents	154	1	75/60	192.5
Teachers	154	1	30/60	77
Community Providers	20	1	75/60	25
Total				487

Dated: November 23, 2001.

Julie Fishman,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control, and Prevention.

[FR Doc. 01–29620 Filed 11–27–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0435]

International Conference on Harmonisation; Draft Guidance on Electronic Common Technical Document Specification; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Electronic Common Technical Document Specification'' (eCTD). The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance defines the means for industry-to-agency transfer of regulatory information that will facilitate the creation, review, life cycle

management, and archiving of the electronic submission. The draft guidance is intended to assist industry in transferring electronically their marketing applications for human drug and biological products to a regulatory authority.

DATES: Submit written or electronic comments on the draft guidance by February 26, 2002. 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, or 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, 301–827–3844, FAX 888–CBERFAX. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Robert Yetter, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0373, or Gregory V. Brolund, Center for Drug Evaluation and Research (HFD–070), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3516.

Regarding the ICH: Janet J. Showalter, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0864.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA). The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, the Canadian Health Protection Branch, and the European Free Trade Area.

In accordance with FDA's good guidance practices regulation (GGP) (21 CFR 10.115), this document is being called a guidance, rather than a guideline.

To facilitate the process of making ICH guidances available to the public, the agency has changed its procedure for publishing ICH guidances. As of April 2000, we no longer include the text of ICH guidances in the **Federal Register**. Instead, we publish a notice in the **Federal Register** announcing the availability of an ICH guidance. The ICH guidance will be placed in the docket and can be obtained through regular agency sources (see the **ADDRESSES** section). Draft guidances are left in the original ICH format. The final guidance is reformatted to conform to the GGP style before publication.

In June 2001, the ICH Steering Committee agreed that a draft guidance entitled ''Electronic Common Technical Document Specification'' should be made available for public comment and testing. The draft guidance is the product of the Multidisciplinary Group 2 (M2) Expert Working Group (EWG) of the ICH. Comments about this draft guidance will be considered by FDA and the M2 EWG and another draft will be published for comment (Step 2).

The draft guidance provides guidance on industry-to-agency electronic transfer of marketing applications for human drug and biological products. The draft guidance defines the means for industry-to-agency transfer of regulatory information that will facilitate the creation, review, life cycle management, and archiving of the electronic submission. The draft guidance is intended to assist industry in transferring their marketing applications for human drug and biological products to a regulatory authority.

This draft guidance, when finalized, will represent the agency's current thinking on ''Electronic Common Technical Document Specification.'' 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 (addresses above) written or electronic comments on the draft guidance by February 26, 2002. 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 draft guidance and received comments may be seen in the office above 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/m2/ or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: October 30, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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