Dated: August 18, 2000.

Nancy Cheal,

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

[FR Doc. 00–21611 Filed 8–23–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY–67–00]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–7090. Send written comments to CDC, Desk Officer; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Project

2001 National Health Interview Survey, Basic Module (0920–0214)—Revision—The National Center for Health Statistics (NCHS)—The annual National Health Interview Survey (NHIS) is a basic source of general statistics on the health of the U.S. population. Due to the integration of health surveys in the Department of Health and Human Services, the NHIS also has become the sampling frame and first stage of data collection for other major surveys, including the Medical Expenditure Panel Survey, the National Survey of Family Growth, and the National Health and Nutrition Examination Survey. By linking to the NHIS, the analysis potential of these surveys increases. The NHIS has long been used by government, university, and private researchers to evaluate both general health and specific issues, such as cancer, AIDS, and childhood immunizations. Journalists use its data to inform the general public. It will continue to be a leading source of data for the Congressionally-mandated ''Health US'' and related publications, as well as the single most important source of statistics to track progress toward the National Health Promotion and Disease Prevention Objectives, ''Healthy People 2000.''

Because of survey integration and changes in the health and health care of the U.S. population, demands on the NHIS have changed and increased, leading to a major redesign of the annual core questionnaire, or Basic Module, and a redesign of the data collection system from paper questionnaires to computer assisted personal interviews (CAPI). Those redesigned elements were partially implemented in 1996 and fully implemented in 1997 and are expected to be in the field until 2006. This clearance is for the fifth full year of data collection using the Basic Module on CAPI, and for implementation of the second ''Periodic Module'', which include additional detail questions on conditions, access to care, disabilities, and health care utilization. The ''Periodic Module'', will repeat a similar survey conducted in 1992, and will help track many of the Health People 2010 objectives. This data collection, planned for January–December 2001, will result in publication of new national estimates of health statistics, release of public use micro data files, and a sampling frame for other integrated surveys. The annualized burden is 48,600 hours.

Questionnaire (respondent)	Number of respondents	Number of responses per respondent	Average burden per respondent (in hours)
Family core (adult family member)	42,000	1	21/60
Adult core (sample adult)	42,000	1	21/60
Child core (adult family member)	18,000	1	15/60
Periodic module (sample adult)	42,000	1	21/60
All households	42,000	1	110/60

Dated: August 18, 2000.

Nancy Cheal,

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

[FR Doc. 00–21612 Filed 8–23–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–0186]

International Conference on Harmonisation; Draft Guidance on M4 Common Technical Document; 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 ''M4 Organization of the Common Technical Document for the Registration of Pharmaceuticals for Human Use'' (M4 Common Technical Document). The draft guidance was developed under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance, which is being made available simultaneously in four parts, describes a harmonized format and content for new product applications (including applications for biotechnology-derived products) for submission to the regulatory authorities in the three ICH regions. The M4 Common Technical Document is intended to reduce the time and resources used to compile applications, ease the preparation of electronic submissions, facilitate regulatory reviews and communication with the applicant, and simplify the exchange of regulatory information among regulatory authorities.

DATES: Submit written comments on the draft guidance by September 30, 2000.

ADDRESSES: 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. Copies of the draft guidance are available on the Internet at http://www.fda.gov/cder/guidance/index.htm or at http://www.fda.gov/cber/publications.htm. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers