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

Lane, Rockville, MD 20857; or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3844, FAX 888–CBERFAX. Send two self-addressed adhesive labels to assist the office in processing your requests.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: For the safety (nonclinical) components: Joseph J. DeGeorge, Center for Drug Evaluation and Research (HFD–24), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5476.

For the quality components: Charles P. Hoiberg, Center for Drug Evaluation and Research (HFD–810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857,301–594–2570; and Neil D. Goldman, Center for Biologics Evaluation and Research (HFM–20), Food and Drug Administration,1401 Rockville Pike, Rockville, MD 20852, 301–827–0377.

For the efficacy (clinical) sections: Robert J. DeLap, Center for Drug Evaluation and Research (HFD–105), Food and Drug Administration, 9201 Corporate Blvd., Rockville, MD 20850, 301–827–2250.

Regarding the ICH: Janet J. Showalter, Office of International Programs (HFY–20), 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.

ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. ICH is concerned with harmonization 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 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 Therapeutics Products Programme, and the European Free Trade Area.

The ICH process has achieved significant harmonization of the technical requirements for the approval of pharmaceuticals for human use in the three ICH regions. However, until recently, the application documents in the three ICH regions had not been examined, and there are different requirements in the regions for the composition and organization of product applications. As a result, three Expert Working Groups for Quality, Safety, and Efficacy have been developing harmonized guidance for the content and format of common sections of an application, called the ''common technical document.'' Once finalized, the guidance ''M4 Common Technical Document'' will describe an acceptable format and content for applications for human pharmaceuticals that, once supplemented with regional particulars, can be used with new products for submission to the regulatory authorities in the three ICH regions. In the **Federal Register** of February 11, 2000 (65 FR 7024), the agency announced the availability of initial components of the draft guidance and requested public comment. Comments from that announcement were considered in developing this draft guidance.

In July 2000, the ICH Steering Committee agreed that a draft guidance entitled ''M4 Common Technical Document'' should be made available for public comment. Comments about the draft guidance will be considered by FDA and the appropriate expert working group.

To facilitate the process of making ICH guidances available to the public, the agency is changing its procedures for publishing ICH guidances. Since 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 is placed in the docket and can be obtained through regular agency sources (see the **ADDRESSES** section). The draft guidance is left in the original ICH format. The final guidance will be reformatted to conform to the GGP style before publication.

In accordance with FDA's good guidance practices (GGP) (62 FR 8961, February 27, 1997), ICH guidance documents are now being called guidances, rather than guidelines.

II. The Common Technical Document

The draft guidance 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 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.

The draft guidance addresses the organization of information presented in new product applications. With appropriate modifications, the draft guidance may be applied to abbreviated or other applications. The draft guidance is not intended to indicate what studies should be included, but merely to indicate an appropriate format for data that are submitted.

The common technical document should be viewed as the common part of a submission for new products, presented in a modular fashion with summaries and tables. It is intended that one of the modules (module I) in the common technical document be reserved as a region-specific module, and thus will not be harmonized.

When finalized, the common technical document modular structure is envisioned as shown in the graphic at the end of this notice and the following table of contents for the document:

Module I: Administrative Information and Prescribing Information Documents are region specific; for example, application forms, prescribing information.

Module II: Common Technical Document Summaries

A. Overall Common Technical Document Table of Contents

B. Overall Summaries

1. Introduction

2. Quality Overall Summary

3. Nonclinical Overall Summary

4. Clinical Overall Summary

C. Nonclinical Summaries

1. Pharmacology

a. Written summary

b. Tabulated summary
2. Pharmacokinetics
a. Written summary
b. Tabulated summary
3. Toxicology
a. Written summary
b. Tabulated summary
D. Clinical Written Summary
1. Biopharmaceutics and Associated Analytical Methods
2. Clinical Pharmacology
3. Clinical Efficacy
4. Clinical Safety
5. Synopses of Individual Studies
Module III: Quality
A. Table of Contents
B. Body of Data
Module IV: Nonclinical Study Reports
A. Table of Contents
B. Study Reports
C. Key Literature References
Module V: Clinical Study Reports
A. Table of Contents
B. Study Reports
C. Key Literature References

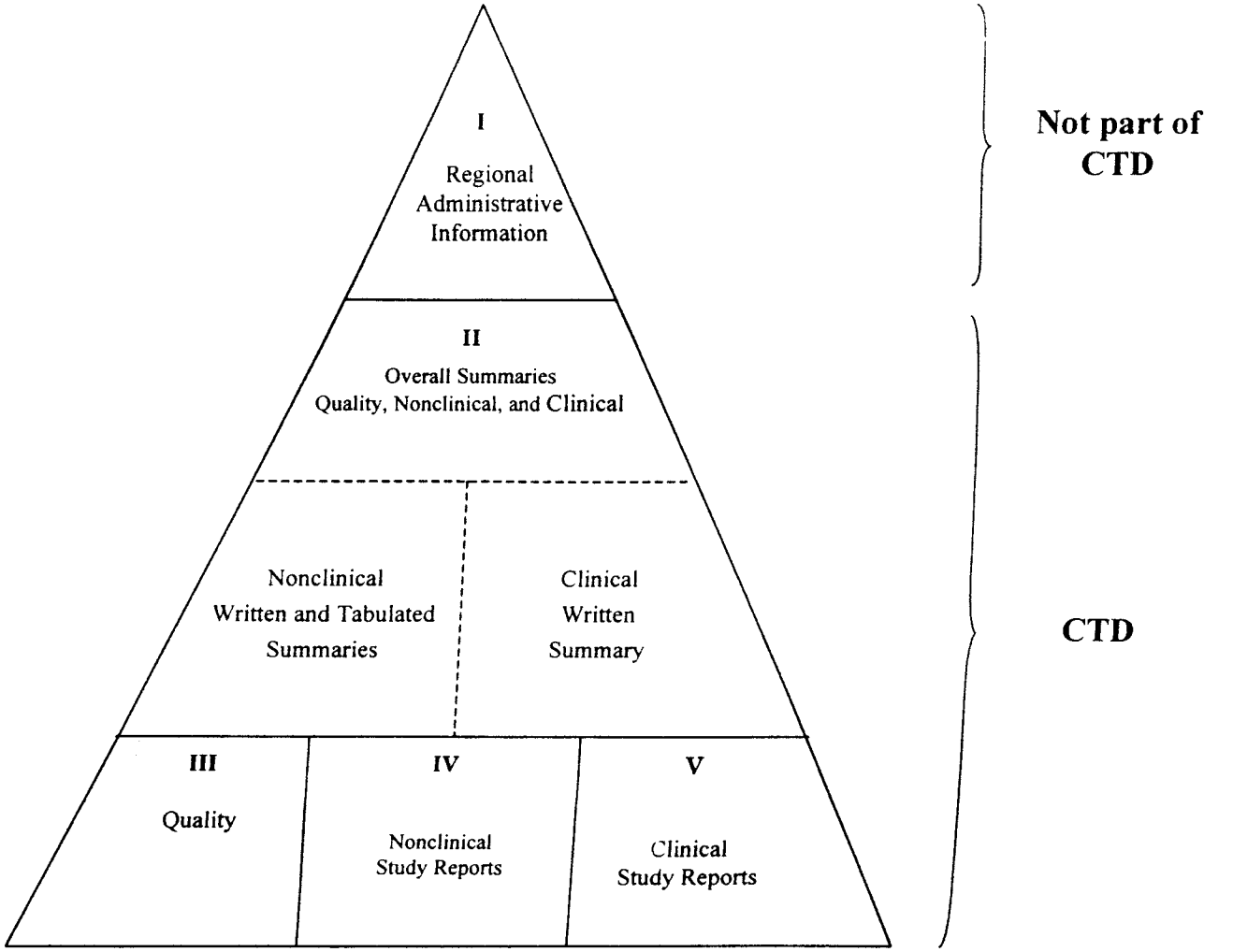
The draft guidance being made available with this notice is the product of the ICH Common Technical Document Expert Working Groups for Quality, Safety, and Efficacy. To facilitate the handling of the guidance, it is being made available in four parts: (1) A description of the organization of the M4 Common Technical Document; (2) the Quality section; (3) the Safety, or nonclinical section; and (4) the Efficacy, or clinical section.

This draft guidance represent the agency's current thinking on the content and format of a common application for new products (i.e., the common technical document). The draft guidance 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, regulations, or both.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance by September 30, 2000. 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 components of the draft guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

BILLING CODE 4160–01–F

Diagrammatic Representation of the ICH Common Technical Document



Dated: August 15, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–21563 Filed 8–23–00; 8:45 am]

BILLING CODE 4160–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 12, 2000, 1 p.m. to 5:30 p.m.

Location: Hyatt Regency, One Bethesda Metro Center, Bethesda, MD.

Contact Person: Karen M. Templeton-Somers, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, e-mail: SomersK@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12542. Please call the Information Line for up-to-date information on this meeting.

Agenda: The subcommittee will discuss parameters used in oncology for extrapolation from the adult to the pediatric setting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by September 6, 2000. Oral presentations from the public will be scheduled between approximately 1:15 p.m. and 2:15 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 6, 2000, 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. After the scientific presentations, a 30-minute open public session may be conducted for interested persons who have submitted their request to speak by September 6, 2000, to address issues specific to the topic before the subcommittee.

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

Dated: August 15, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–21561 Filed 8–23–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4561–N–57]

Notice of Proposed Information Collection: Comment Request; Request Voucher for Grant Payment—LOCCS Voice Response Access Authorization

AGENCY: Office of the Administration for Chief Financial Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be 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.

DATES: *Comments due:* October 23, 2000.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number (2535–0102) should be sent to: Wayne Eddins, Reports Management Officer, Department or Housing and Urban Development, 451 7th Street, SW, L'Enfant Plaza Building, Room 800a, Washington, D.C. 20410.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, Q, Department of Housing and Urban Development, 451 Seventh Street, Southwest, Washington, DC 20410; e-mail Wayne_Eddins@HUD.gov; telephone (202) 708–2374 (this is not a toll-free number) for copies of the proposed forms and other available information.

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

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: Request Voucher For Grant Payment—LOCCS Voice Response Access Authorization.

OMB Control Number, if applicable: 2535–0102.

Description of the need for the information and proposed use: Request vouchers are used by recipients to request distribution of grant funds through access to the Department's voice activated payment system. Information collected will be used as mechanism to safeguard Federal funds and to facilitate the payment of funds to recipients.

Agency form numbers, if applicable: HUD–27053, HUD–27053–A/B, HUD–27054.

Estimation of the total number of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: An estimation of the total number of hours needed to prepare the information collection is 41,133, number of respondents is 2,000, frequency of response is on occasion, and the hours per response is 0.17.

Status of the proposed information collection: Extension without change of a currently approved collection.

Authority: Section 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: August 18, 2000.

Wayne Eddins,

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

[FR Doc. 00–21606 Filed 8–23–00; 8:45 am]

BILLING CODE 4210–01–M