would be duplicating burden and difficult to calculate separately. The following recordkeeping estimates for the number of recordkeepers, total annual records, and hours per record are based on information provided by industry, and FDA experience.

FDA estimates the burden of this information collection as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
1270.31(a) and 1270.31(b)	2	2	4	1.0	4
1270.33(a), (f), and (h), and 1270.35(a) and (b)	2	498	996	1.0	996
1270.35(c)	2	1,975	3,950	1.0	3,950
1270.35(d)	2	65	130	1.0	130
Total					5,080

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: July 28, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–19864 Filed 8–4–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1407]

International Conference on Harmonisation; Draft Guidance on Safety Pharmacology Studies for Human Pharmaceuticals; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''S7 Safety Pharmacology Studies for Human Pharmaceuticals.'' The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use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 The draft guidance describes general principles and recommendations for safety pharmacology evaluations. The draft guidance is intended to help protect clinical trial participants and patients receiving marketed products from potential adverse reactions to pharmaceuticals and to avoid unnecessary use of animals and other resources.

DATES: Submit written comments on the draft guidance by September 6, 2000.

ADDRESSES: Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Copies of the draft guidance are available on the Internet at http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/cber/publications.htm. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the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: Joseph J. DeGeorge, Center for Drug Evaluation and Research (HFD–24), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5476.

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: 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 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 (GGP's) (62 FR 8961, February 27, 1997), 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 is changing its procedure for publishing ICH guidances. Beginning April 2000, we will no longer include the text of ICH guidances in the **Federal Register**. Instead, we will 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). The draft guidance will be left in the original ICH format. The final guidance will be reformatted to conform to GGP style before publication.

In March 2000, the ICH Steering Committee agreed that a draft guidance entitled ''S7 Safety Pharmacology Studies for Human Pharmaceuticals'' should be made available for public comment. The draft guidance is the product of the Safety Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Safety Expert Working Group.

The draft guidance describes general principles and recommendations for safety pharmacology evaluations. The draft guidance is intended to help protect clinical trial participants and patients receiving marketed products from potential adverse reactions to pharmaceuticals and avoid unnecessary use of animals and other resources. The draft guidance generally applies to new chemical entities and biotechnology-derived products for human use. The draft guidance may be applied to marketed pharmaceuticals when appropriate. For example, adverse clinical events, a new patient population, or a new route of administration may raise concerns not previously addressed.

This draft guidance represents the agency's current thinking on safety pharmacology studies for human pharmaceuticals. 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, regulations, or both.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance by September 6, 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 draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 31, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–19941 Filed 8–2–00; 3:33 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

National Native American Emergency Medical Services Association

AGENCY: Indian Health Service, IHS.

ACTION: Notice of single source cooperative agreement with the National Native American Emergency Medical Services Association.

SUMMARY: The Indian Health Service (IHS) announces the award of a cooperative agreement to the National Native American Emergency Medical Services Association (NNAEMSA) for a demonstration project to improve emergency medical services for Native American people by improving communications between the IHS and the Native American Emergency Medical Services providers and by supporting an Annual Educational Conference. The cooperative agreement is for a five-year project period effective July 1, 2000, to June 30, 2005. Total funding for the project is $280,000.

The award is issued under the authority of the Public Health Service Act, Section 301(a), and is included under the Catalog of Federal Domestic Assistance number 93.933.

The specific objectives of the project are:

1. The Association will publish, at least twice a year, a newsletter for members. The newsletter will be available in both hard copy and electronically.

2. The Association will present an Annual Educational Conference which supports training and continuing education for Native American EMS providers.

3. The Association will establish links with other national Indian organizations and with professional groups to serve as advocates for the EMS providers who work with Native American people nationwide.

Justification for Single Source

This project has been awarded on a non-competitive single source basis. NNAEMSA is the only nationwide organization that specifically represents approximately 70 individual Native American EMS programs. These EMS programs provide care to over half-million Native American people who live on Indian reservations or who live in non-reservation areas with significant Native American populations. The population served by these programs is the same as IHS's user population.

Use of Cooperative Agreement

A cooperative agreement has been awarded because of anticipated substantial programmatic involvement by IHS staff in the project. The substantial programmatic involvement is as follows:

1. IHS staff will approve articles to be included in the newsletters and may, as requested by the Association, provide articles.

2. Working with the Association, IHS staff will be involved in the development of the Annual Educational Conference to include topics of concern to the Agency and will be included in presentations as requested.

FOR FURTHER INFORMATION CONTACT: For program information, contact W. Craig Vanderwagen, M.D., Director, Division of Clinical and Preventive Services, Office of Public Health, Indian Health Service, Room 6A–55, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443–3024. For grants information, contact Ms. M. Kay Carpentier, Grants Management Officer, Division of Acquisitions and Grants Management, Indian Health Service, Suite 100, 12300 Twinbrook Parkway, Rockville, Maryland 20852, telephone (301) 443–5204.

Dated: July 21, 2000.

Michel E. Lincoln,

Acting Director.

[FR Doc. 00–19865 Filed 8–4–00; 8:45 am]

BILLING CODE 4160–16–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4561–N–48]

Notice of Submission of Proposed Information Collection to OMB Affirmative Fair Housing Marketing Plan, Form HUD–935.2

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been 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 Date:* September 6, 2000.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval number (2529–0013) and should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, Q, Department of Housing and