

In March 2000, the ICH Steering Committee agreed that a draft guidance entitled "S7 Safety Pharmacology Studies for Human Pharmaceuticals" should be made available for public comment. The draft guidance is the product of the Safety Expert Working Group of the ICH.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The draft guidance describes general principles and recommendations for safety pharmacology evaluations. The draft guidance is intended to help protect clinical trial participants and patients receiving marketed products from potential adverse reactions to pharmaceuticals and avoid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 The draft guidance generally applies to new chemical entities and biotechnology-derived products for human use. The draft guidance may be applied to marketed pharmaceuticals when appropriate.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This draft guidance represents the agency's current thinking on safety pharmacology studies for human pharmaceuticals.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Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance by September 6, 2000.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 The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.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