I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities, industry associations, and individual sponsors to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seeking scientifically based harmonized technical requirements for the development of pharmaceutical products. One of the goals of harmonization is to identify and reduce the differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use for several years to develop harmonized technical requirements for the registration of human pharmaceutical products among the European Union, Japan and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the registration of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH meetings are held under the auspices of the Office International des Epizooties (OIE). The VICH Steering Committee is composed of member representatives from the European Commission; the European Medicines Evaluation Agency; the European Federation of Animal Health; the Japanese Veterinary Pharmaceutical Association; the Japanese Ministry of Agriculture, Forestry and Fisheries; the U.S. Animal Health Institute; the U.S. FDA; and the U.S. Department of Agriculture.

Four observers are eligible to participate in the VICH Steering Committee: One representative from the Government of Australia/ New Zealand, one representative from industry in Australia/ New Zealand, one representative from MERCOSUR (Argentina, Brazil, Uruguay and Paraguay), and one representative from Federacion Latino-Americana de la Industria para la Salud Animal. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the Confédération Mondiale de L'Industrie de la Santé Animale (COMISA). A COMISA representative participates in the VICH Steering Committee meetings.

The VICH Steering Committee held meetings and agreed that the four draft guidance documents should be made available for public comment. On October 20 through 22, 1998, the Committee agreed to the draft guidance document entitled ''Efficacy of Anthelmintics: General Recommendations.'' On March 16 through 18, 1999, the Committee agreed on the three draft guidance documents entitled ''Efficacy of Anthelmintics: Specific Recommendations for Bovines,'' ''Efficacy of Anthelmintics: Specific Recommendations for Ovines,'' and ''Efficacy of Anthelmintics: Specific Recommendations for Caprines.''

The draft guidance entitled ''Efficacy of Anthelmintics: General Recommendations'' is intended to standardize and simplify the methods used for the effectiveness evaluation of new anthelmintics and generic copies for use in domesticated animals. Animal welfare will benefit by the elimination of duplicate studies, which will reduce the number of animals required for necessary studies. Likewise this will benefit the industry by reducing research and development costs. The three draft guidances entitled ''Efficacy of Anthelmintics: Specific Recommendations for Bovines,'' ''Efficacy of Anthelmintics: Specific Recommendations for Ovines,'' and ''Efficacy of Anthelmintics: Specific Recommendations for Caprines'' should be read in conjunction with the ''Efficacy of Anthelmintics: General Recommendations (EAGR).'' The guidances for bovines, ovines, and caprines are part of the EAGR, and the aim of these three draft guidances is to: (1) Be more specific for certain issues not discussed in the general guidance, (2) highlight differences with the EAGR on efficacy data recommendations, and (3) give explanations for disparities with the EAGR. Comments about the draft guidance documents will be considered by the FDA and the VICH Anthelmintic Working Group. Ultimately, FDA intends to adopt the VICH Steering Committee's final guidances and publish them as future guidances.

These draft documents, developed under the VICH process, have been revised to conform to FDA's good guidance practices regulations (62 FR 8961, February 27, l997). For example, the documents have been designated ''guidance'' rather than ''guideline.'' Because guidance documents are not binding, unless specifically supported by statute or regulation, mandatory words such as ''must,'' ''shall , '' and ''will'' in the original VICH documents have been substituted with ''should.'' Similarly, words such as ''requirement'' or ''acceptable'' or phrases such as ''minimum standards'' or ''minimum needed'' have been replaced by ''recommendation'' or ''recommended'' as appropriate to the context. Additionally, the term(s) ''veterinary medicinal products'' and ''veterinary pharmaceuticals products'' may require revision to be consistent with product terms used in other VICH guidance documents.

These draft documents represent current FDA thinking on efficacy requirements for anthelmintic medicinal products. These documents do not create or confer any rights for or on any person and will not operate to bind FDA or the public. Alternate approaches may be used if they satisfy the requirements of applicable statutes, regulations, or both.

II. Comments

Interested persons should submit written comments on or before August 16, 1999 to the Dockets Management Branch (address above) regarding the guidance documents. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday, except for Federal Holidays.

Dated: July 12, 1999.

Margaret M. Dotzel,

Acting Assoicate Commissioner for Policy Coordination.

[FR Doc. 99–18166 Filed 7–13–99; 12:06 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)–443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: National Health Service Corps (NHSC) Professional Training and Information Questionnaire (PRIQ) OMB No. 0915–0208: Revision

The Health Resources and Services Administration, Bureau of Primary Health Care, NHSC, assists medically underserved communities through the placement of primary health care professionals in health professional shortage areas.

The PTIQ is used to collect data related to professional issues, family concerns, and assignment preferences from NHSC obligated Scholarship Program Recipients including physicians, physician assistants (PAs), nurse practitioners (NPs), certified nurse midwives (CNMs), and other disciplines in the current year's placement cycle. These data are used to match an individual health care professional with the most appropriate clinical practice setting.

The PTIQ will be mailed twelve months in advance of the intended service availability date.

The burden estimate is as follows:

Type of respondent	Number of respondents	Responses per respondent	Hours per response (minutes)	Total hour burden
Health care professionals	339	1	12	68
Total	339			68

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Wendy A. Taylor, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: July 12, 1999.

James J. Corrigan,

Associate Administrator for Management and Program Support.

[FR Doc. 99–18123 Filed 7–15–99; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4340–FA–09]

FY 1998 Comprehensive Improvement Assistance Program; Announcement of Funding Awards

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Announcement of funding awards.

SUMMARY: In accordance with section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989, this announcement notifies the public of funding decisions made by the Department for funding under the FY 1998 Super Notice of Funding Availability (SuperNOFA) for the Comprehensive Improvement Assistance Program. This announcement contains the names and addresses of the competition award recipients and the amounts of the awards.

FOR FURTHER INFORMATION CONTACT: Michael Diggs, Director, Grants Management Center, Department of Housing and Urban Development, 501 School Street, SW, Suite 800, Washington, DC 20410, telephone (202) 358–0221, extension 101. (This is not a toll-free number). A telecommunication device for hearing- and speech-impaired individuals (TTY) is available at 1–800–877–8339 (Federal Information Relay Service).

SUPPLEMENTARY INFORMATION:

The Comprehensive Improvement Assistance Program is authorized by sec. 14, United States Housing Act of 1937 (42 U.S.C. 14371); Sec. 7 (d) Department of Housing and Urban Development Act (42 U.S.C. 3535(d)).

The objective of the Comprehensive Improvement Assistance Program (CIAP) is to provide funds to improve the physical condition and upgrade the management and operation of existing Public projects to assure that they continue to be available to serve low-income families.

On March 31, 1998 (63 FR 15566), the Department published a SuperNOFA in the **Federal Register** informing Public Housing Agencies that own or operate fewer than 250 units of the availability of FY 1998 CIAP funding. The FY 1998 awards announced in this Notice were selected for funding consistent with the provisions of the SuperNOFA.

In accordance with section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Action of 1989 (103 Stat. 1987, 42 U.S.C. 3545), the Department is hereby publishing, in this notice, the names and addresses of the PHAs that received funding awards under the FY 1998 CIAP SuperNOFA, and the amount of the awards. This information is set forth in Appendix A to this notice.

The Catalog of Federal Domestic Assistance number for the CIAP Program is 14.852.

Dated: July 2, 1999.

Harold Lucas,

Assistant Secretary for Public and Indian Housing.

Appendix A

RECIPIENTS OF FISCAL YEAR 1998 COMPREHENSIVE IMPROVEMENT ASSISTANCE PROGRAM AWARDS

Applicant name	Address	Amount funded
ALBERTVILLE HA	P.O. BOX 1126, ALBERTVILLE, AL 35950–0000	$200,000.00
HA OF THE CITY OF ALICEVILLE	P.O. BOX 485, ALICEVILLE, AL 35442–0485	500,000.00
HA ARAB	P.O. BOX 452, ARAB, AL 35016–0000	157,500.00
HA ASHFORD	100 BRUNNER STREET, ASHFORD, AL 36302–0000	50,000.00
HA OF THE CITY OF COLUMBIA	100 BRUNNER STREET, ASHFORD, AL 36312–0000	42,500.00
HA OF THE TOWN OF ASHLAND	155 RUNYAN COURT, ASHLAND, AL 36251,	187,000.00
HA OF THE CITY OF ATHENS	5TH AVE., BLDG J, ATHENS, AL 35611–0853	235,000.00
HA BAY MINETTE	400 SOUTH STREET, BAY MINETTE, AL 36507–0000	267,599.00
HA OF THE TOWN OF BERRY	P.O. BOX 387, BERRY, AL 35546–0387	90,000.00