labeled with sufficient information to ensure their safe use.

FDA estimates the burden of complying with the information collection provisions of the agency's color additive regulations as follows:

Estimated Annual Reporting Burden

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Response	Total Hours	Total Operating & Maintenance Costs
70.25	2	1	2			
71.1	2	1	2	1,700	3,415	$6,000
Total	2				3,415	$6,000

There are no capital costs associated with this collection.

This estimate is based on the number of new color additive petitions received in 1994. Although the burden varies with the type of petition submitted, a color additive petition involves analytical work and appropriate toxicology studies, as well as the work of drafting the petition itself. Because labeling requirements under § 70.25 for a particular color additive involve information required as part of the color additive petition safety review process, the estimate for the number of respondents is the same for § 70.25 as for § 71.1, and the burden hours for labeling are included in the estimate for § 71.1.

Dated: February 27, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–5212 Filed 3–5–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96D–0067]

Guidance for Industry, Designing Clinical Programs for Developing Human Drugs, Medical Devices, or Biological Products Intended for the Treatment of Rheumatoid Arthritis; Availability of Draft Guidance; Notice of Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''Draft Guidance for Industry in Designing Clinical Programs for Developing Human Drugs, Medical Devices, or Biological Products Intended for the Treatment of Rheumatoid Arthritis.'' The agency is also announcing a public workshop to discuss the draft guidance document. The draft guidance document was prepared by the Rheumatology Working Group comprised of members from: The Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health. The workshop will enable experts in rheumatology clinical trials and interested representatives of industry, academia, and the public to exchange ideas on developing and assessing new treatment modalities for rheumatoid arthritis (RA) and to discuss the types of claims that might be reasonably pursued and the data necessary to support such claims.

DATES: The public workshop will be held Wednesday, March 27, 1996, from 8 a.m. to 6 p.m. There is no registration fee for the workshop, but advance registration is requested. Interested parties are encouraged to register early because space is limited. Written comments on the draft guidance for consideration at the workshop should be submitted by March 22, 1996. The administrative docket will remain open until May 30, 1996, for the submission of written comments, data, information, or views on the draft guidance or the workshop.

ADDRESSES: The public workshop will be held at the DoubleTree Hotel, 1750 Rockville Pike, Plaza 1 and 2, Rockville, MD 20852. Persons interested in attending should Fax their registration to Rose Cunningham at 301–594–5493. The Fax should include the participant's name and title; organization name, if any; address; and telephone number.

A copy of the draft guidance document entitled ''Draft Guidance for Industry in Designing Clinical Programs for Developing Human Drugs, Medical Devices, or Biological Products Intended for the Treatment of Rheumatoid Arthritis'' is available through the Center for Drug Evaluation and Research's Fax-on-Demand, 301–827–0577 or 800–342–2722, under the index ''Guidance to industry,'' document no. 0806. The draft guidance is also available via Internet by connecting to the CDER file transfer protocol server (CDVS2.CDER.FDA.GOV). A transcript of the workshop will be available from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, approximately 10 business days after the workshop at a cost of 10¢ per page.

Written comments on the draft guidance or the workshop should be submitted to the Dockets Management Branch (HFA–305), 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Rose Cunningham, Center for Drug Evaluation and Research (HFD–6), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5470.

SUPPLEMENTARY INFORMATION: A variety of new treatment modalities are being developed for RA, and many of these are anticipated to have beneficial effects that are different from traditional agents. However, uncertainty exists among experts in rheumatology clinical trials about the types of claims that might be reasonably pursued for these agents and what data would be necessary to support such claims. In addition, there is a need to identify appropriate outcome measures for RA, including composite indices, quality of life measures, and radiographic techniques. Parallel developments of treatment modalities for RA in the human drug, biological, and medical device communities have provided further impetus to the creation of this draft guidance document.

FDA, through its Rheumatology Working Group, has developed a draft guidance document for industry that provides an overview of the kinds of design problems that are encountered in RA trials intended for product

development, and offers a variety of suggested approaches that may be considered for improving the reliability, robustness, and clinical relevance of such trials. FDA is sponsoring a public workshop to provide an opportunity for experts in rheumatology clinical trials and interested representatives of industry, academia, and the public to discuss the working draft of the guidance document and to exchange ideas on developing and assessing new treatment modalities for RA as well as the types of claims that might be reasonably pursued and the data necessary to support such claims.

After consideration of all data, information, or views submitted on the draft guidance and at the workshop, FDA will issue a final guidance document and announce its availability with a notice published in the Federal Register.

Dated: February 29, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–5211 Filed 3–5–96; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Ryan White Title IV Grants for Coordinated HIV Services and Access to Research for Children, Youth, Women, and Families

AGENCY: Health Resources and Services Administration (HRSA), PHS.

ACTION: Notice of availability of funds.

SUMMARY: The HRSA announces that applications will be accepted for fiscal year (FY) 1996 funds for grants for projects that enhance access to clinical research trials and other research, and develop and support the provision of coordinated comprehensive services and activities for children, youth, women and families infected/affected by the Human Immunodeficiency Virus (HIV). Projects will be funded to implement programs of family-centered, community-based coordinated care and research for children, youth, women, and families infected/affected by HIV, or those at risk for developing infection. These projects are authorized under, and expected to meet provisions contained within, Section 2671 of the Public Health Service Act [as enacted by Title IV, of the Ryan White Comprehensive AIDS Resource Emergency (CARE) Act of 1990, Public Law 101–381 (42 U.S.C. 300ff–11 *et seq.*)]. Within the HRSA, Ryan White Title IV projects are administered by the Maternal and Child Health Bureau (MCHB).

This program announcement is subject to the appropriation of funds. Applicants are advised that this program announcement is a contingency action being taken to assure that should funds become available for this purpose, they can be awarded in a timely fashion consistent with the needs of the program as well as to provide for even distribution of funds throughout the fiscal year. At this time, given a continuing resolution and the absence of FY 1996 appropriations for the EMSC program, the amount of available funding for this specific grant program cannot be estimated. In addition, reauthorization of the Ryan White CARE Act, currently pending in Congress, could add new Title IV grant requirements in addition to those included in this notice.

The PHS is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS national activity for setting priority areas. Title IV directly addresses the Healthy People 2000 objectives related to the priority area of HIV infection. Potential applicants may obtain a copy of *Healthy People 2000* (Full Report; Stock Number 017–001–0474–0) or *Healthy People 2000* (Summary Report: Stock No. 017–001–00473–1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325 (telephone 202 783–3238).

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products. In addition, Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases any portion of a facility) in which regular routine education, library, day care, child care or early development services are provided to children.

ADDRESSES: Grant applications for the Ryan White Title IV Program (PHS form #5161–1, approved under OMB #0937–0189) must be obtained from and submitted to: Mona D. Thompson, Grants Management Branch, Office of Program Support, Maternal and Child Health Bureau, HRSA, Room 18–12, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443–3429. You must obtain application materials in the mail.

Federal Register notices and application guidance for MCHB programs are available on the World Wide Web via the Internet at address: http://www.os.dhhs.gov/hrsa/mchb. Click on the file name you want to download to your computer. It will be saved as a self-extracting (Macintosh or) Wordperfect 5.1 file. To decompress the file once it is downloaded, type in the file name followed by a <return>. The file will expand to a Wordperfect 5.1 file. If you have difficulty accessing the MCHB Home Page via the Internet and need technical assistance, please contact Linda L. Schneider at 301–443–0767 or ''lschneider@hrsa.ssw.dhhs.gov''.

DATES: The application deadline date is April 19, 1996. Competing applications will be considered to be on time if they are:

(1) Received on or before the deadline date, or

(2) Postmarked on or before deadline date and received in time for orderly processing.

As proof of timely mailing, applicants should obtain a legibly dated receipt from the commercial carrier or the U.S. Postal Service; private metered postmarks will not be accepted as proof of timely mailing.

Late applications not accepted for processing or those sent to an address other than specified in the **ADDRESSES** section will be returned to the applicant.

FOR FURTHER INFORMATION CONTACT: Additional information regarding technical and program issues may be obtained from: the Division of Services for Children with Special Health Needs, Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18A–19, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–9051. Requests for information concerning business management issues should be directed to: Sandra Perry, Acting Grants Management Officer (GMO), Maternal and Child Health Bureau, at the address specified in the **ADDRESSES** section.

SUPPLEMENTARY INFORMATION:

Program Background and Objectives

The Pediatric AIDS Program was initiated in 1988. The program grew from 13 projects funded at $4.4 million to a total of 59 projects funded at $25.4 million in FY 1995. Since 1988, the program has evolved from a primary focus on the coordination of services for the management and care of infected children and their families to also address the broader prevention and care needs of youth and women infected/affected by HIV. In FY 1994, Congress funded the Pediatric AIDS Program under section 2671, Title IV of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act 1990, Public Law 101–381 (Title IV). As a result of