Attachment I

The following DHHS regulations apply to all applicants/grantees under the National Youth Sports Program:

Title 45 of the *Code of Federal Regulations:*

Part 16—Procedures of the Departmental Grant Appeals Board
Part 74—Administration of Grants (non-governmental)
Part 74—Administration of Grants (state and local governments and Indian Tribal affiliates):
Sections
74.62(a) Non-Federal Audits
74.173 Hospitals
74.174(b) Other Nonprofit Organizations
74.304 Final Decisions in Disputes
74.710 Real Property, Equipment and Supplies
74.715 General Program Income
Part 75—Informal Grant Appeals Procedures
Part 76—Debarment and Suspension form Eligibility for Financial Assistance
Subpart F—Drug Free Workplace Requirements
Part 80—Non-discrimination Under Programs Receiving Federal Assistance through the Department of Health and Human Services, Effectuation of Title VI of the Civil Rights Act of 1964
Part 81—Practice and Procedures for Hearings Under Part 80 of this Title
Part 84—Non-discrimination on the Basis of Handicap in Programs
Part 86—aNondiscrimination on the basis of sex in the admission of individuals to training programs
Part 91—Non-discrimination on the basis of Age in Health and Human Services Programs or Activities Receiving Federal Financial Assistance
Part 92—Uniform Administrative Requirements for Grants and Cooperative Agreements to States and Local Governments (Federal Register, March 11, 1988)
Part 93—New Restrictions on Lobbying
Part 100—Intergovernmebntal Review of Department of Health and Human Services Programs and Activities

Certification Regarding Environmental Tobacco Smoke

Public Law 103–227, Part C—Environmental Tobacco Smoke, also known as the Pro-Children Act of 1994 (Act), requires that smoking not be permitted in any portion of any indoor facility owned or leased or contracted for by an entity and used routinely or regularly for the provision of health, day care, education, or library services to children under the age of 18, if the services are funded by Federal programs either directly or through State or local governments, by Federal grant, contract, loan, or loan guarantee. The law does not apply to children's services provided in private residences, facilities funded solely by Medicare or Medicaid funds, and portions of facilities used for inpatient drug or alcohol treatment. Failure to comply with the provisions of the law may result in the imposition of a civil monetary penalty of up to $1000 per day and/or the imposition of an administrative compliance order on the responsible entity.

By signing and submitting this application the applicant/grantee certifies that it will comply with the requirements of the Act. The applicant/grantee further agrees that it will require the language of this certification be included in any subawards which contain provisions for children's services and that all subgrantees shall certify accordingly.

[FR Doc. 96–5148 Filed 3–5–96; 8:45 am]

BILLING CODE 4184–01–M

Food and Drug Administration

[Docket No. 95N–0288]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995, Federal agencies are required to publish a notice in the Federal Register concerning each collection of information and allow 60 days for public comment in response to the notice. This notice solicits comments on requirements relating to the approval and labeling of color additives.

DATES: Submit written comments on the information collection requirements by May 6, 1996.

ADDRESSES: Submit written comments on the information collection requirements to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Mark L. Pincus, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–443–4055.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c). To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Sections 70.25 *Labeling requirements for color additives (other than hair dyes)* (21 CFR 70.25) and 71.1 *Petitions* (21 CFR 71.1) (OMB Control Number 0910–0185—Extension)

Section 721(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379e) provides that a color additive shall be deemed to be unsafe unless the additive and its use are in conformity with a regulation that describes the condition(s) under which the additive may safely be used, or unless the additive and its use conform to the terms of an exemption for investigational use issued under section 721(f) of the act. Color additive petitions are submitted by individuals or companies to obtain approval of a new color additive or a change in the conditions of use permitted for a color additive that is approved already. Section 71.1 specifies the information that a petitioner must submit in order to establish the safety of a color additive and to secure the issuance of a regulation permitting its use.

FDA scientific personnel review color additive petitions to ensure that the intended use of the color additive in or on food, drugs, cosmetics, and medical devices is suitable and safe. Color additive petitions were specifically provided for by Congress when it enacted the Color Additive Amendments of 1960 (Pub. L. 94–295). If FDA stopped accepting color additive petitions or stopped requiring them to contain the information specified in § 71.1, the number of new color additives approved would decrease.

FDA's color additive labeling requirements in § 70.25 require that color additives that are to be used in foods, drugs, devices, or cosmetics be

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