9. Training and Technical Assistance Plan (not scored).

10. Site visits by CDC staff may be conducted before final funding decisions are made. A fiscal Recipient Capability Assessment (RCA) may be required of some applicants before funds are awarded.

Dated: June 24, 1999.

Thena M. Durham,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention.

[FR Doc. 99–16590 Filed 6–29–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

The National Vaccine Program Office (NVPO), of the Centers for Disease Control and Prevention (CDC), Announces the Following Meeting

Name: International Symposium on Combination Vaccines.

Times and Dates: 8:30 a.m.–6 p.m., February 2, 2000. 9 a.m.–6 p.m., February 3, 2000. 8:30 a.m.–5 p.m., February 4, 2000.

Place: Natcher Auditorium, NIH Campus, Bethesda, Maryland.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 500 people.

Purpose: The purpose of the meeting is to fully explore laboratory, clinical, and epidemiologic data integral to developing and licensing new safe and effective combination vaccines.

Matters To Be Discussed: Agenda items will include presentations and discussion regarding: immunogenicity; immune interference; correlates of protection; pre- and post-licensure safety evaluation; combination vaccines vs. simultaneous administration; manufacturing, product testing, and preclinical (animal) evaluation; and overcoming challenges to use of combination vaccines.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Alicia S. Postema, Health Policy Fellow, NVPO, CDC, 1600 Clifton Road, NE, M/S A–11, Atlanta, Georgia 30333, telephone 404/639–4450.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: June 23, 1999.

Carolyn Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 99–16589 Filed 6–29–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Head Start Grants Administration.

OMB No.: 0980–0243.

Description: This part establishes regulations applicable to program administration and grant management for grants under the Head Start Act. The regulations clarify definitions of terms applicable to the administration of the Head Start program. In addition the regulations establish a requirement for grantees to have student accidents insurance and bonding for certain officials. The regulations also require funding recipients to establish written personnel policies, and clarify the limitations on costs of development and administration of Head Start programs.

Respondents: State, Local or Tribal Government.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Appeal	2,186	1	2	4,372
Estimated Total Annual Burden Hours: 4,372.				

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 to 60 days after publication of this document in the **Federal Register.** Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, N.W., Attn: ACF Desk Officer.

Dated: June 24, 1999.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 99–16625 Filed 6–29–99; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[0980–0242]

Submission for OMB Review; Comment Request

Title: Appeal Procedures for Head Start Grantees and Current or Former Delegate Agencies.

OMB No.: 0980–0242.

Description: Section 646 of the Head Start Act requires the Secretary to prescribe procedures insuring that an agency or organization which desires to serve as a delegate agency under the Head Start Act will receive special notice and an opportunity for a timely appeal when an application has been wholly or substantially rejected or when such application has not been acted upon within a period of time deemed reasonable by the Secretary. The rule also describes the actions available prior to the suspension, termination, or reduction of financial assistance or when an application for refunding is denied.

Respondents: State, Local or Tribal Government.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Appeal	10	1	16	160

Estimated total Annual Burden Hours: 160.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 to 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, N.W., Attn: ACF Desk Officer.

Dated: June 22, 1999.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 99–16626 Filed 6–29–99; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–0240]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Extralabel Drug Use in Animals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by July 30, 1999.

ADDRESSES: Submit written comments on the collection of information to Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm 10235, Washington, DC 20503, Attention: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Extralabel Drug Use in Animals—21 CFR Part 530 (OMB Control No. 0910–0325—Extension)

Description: The Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) (Pub. L. 103–396), amended the Federal Food, Drug, and Cosmetic Act (the act), to permit licensed veterinarians to prescribe extralabel use in animals of approved human and new animal drugs. Regulations implementing provisions of AMDUCA were codified in 1996 at part 530 (21 CFR part 530). A provision of these regulations, § 530.22(b), permits FDA to establish a safe level for the extralabel use in animals of an approved human or animal drug when the agency determines there is reasonable probability that this extralabel use may present a risk to the public health. The extralabel use in animals of an approved human or animal drug that results in residues exceeding the safe level is considered an unsafe use of the drug.

In conjunction with the establishment of a safe level, FDA may request development of an acceptable residue detection method for an analysis of residues above any safe level established under this part. In some cases, the sponsor may be willing to provide this methodology, while in others, FDA, the sponsor, the U.S. Department of Agriculture (USDA), States, or a consortium of interested parties may negotiate a cooperative arrangement to develop such a methodology. If no acceptable analytical method is developed, the agency would be permitted to prohibit extralabel use of the drug.

In the **Federal Register** of March 1, 1999 (64 FR 10002), the agency requested comments on the proposed collection of information. In response, FDA received one comment, which included several parts with questions. The comments and questions are listed in the following paragraphs with the agency's responses.

The comment asked: ''How will FDA determine a safe level?'' As stated in the preamble to the final rule, the agency may establish a finite safe level based on all relevant scientific information (61 FR 57732 at 57741, November 7, 1996).

The comment asked: ''What will they use?'' As stated in the rule, the agency may establish a safe level based on the lowest level that can be measured by a practical analytical method; or establish a safe level based on other appropriate scientific technical or regulatory criteria.

The comment asked: ''If data [is] not in the approved information or in [the] general domain, then how will they collect it and who will pay for it?'' As stated in the preamble to the final rule (61 FR 57732), the sponsor may be willing to provide the methodology for residue detection in some cases, while in others, FDA, the sponsor, USDA, States, or a consortium of interested parties may negotiate a cooperative arrangement to develop methodology. Conceivably, a third party who might submit such data could include a distributor or group of distributors who wish to make the drug available for extralabel use.

The comment asked: ''Will they force [a] company to collect the data to establish a safe level?'' FDA has no authority under AMDUCA or its implementing regulations to require a sponsor or any other person to collect data to establish a safe level for extralabel use if the sponsor or other person is not willing to do so. If the agency determines that an extralabel use in animals of a particular human drug or animal drug presents a risk to the public health, or if no required acceptable analytical method has been developed, the agency would be permitted to prohibit extralabel use of the drug.

The comment asked: ''How much data will they demand to be collected ?'' The nature and extent of data necessary to establish a safe level or to develop an