Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: May 9, 2002.

Bob Sargis,

Reports Clearance, Officer.

[FR Doc. 02–12318 Filed 5–16–02; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Project

Title: State Plan for FC, ILP and AA under Title IV–E of the Social Security Act.

OMB No.: 0980–0141.

Description: A State plan is required by sections 471 and 477(b)(2), part IV–E of the Social Security Act (the Act) for each public child welfare agency requesting Federal funding for foster care (FC), independent living services (ILP) and adoption assistance (AA) under the Act. The State plan is a comprehensive description of the nature and scope of the State's program and provides assurance the program will be administered in conformity with the specific requirements stipulated in title IV–E. The plan must include all applicable State statutory, regulatory, or policy references and citations for each requirement as well as documentation to support the references. States may use the pre-print format prepared by the Children's Bureau or a different format, on the condition that the format used includes all of the title IV–E state plan requirements of the law.

Respondents: State and Territorial Agencies (State Agencies) administering or supervising the administration of the title IV–E program.

Annual Burden Estimates: An initial plan is submitted by the State Agency for approval to participate in the title IV–E program. Plan amendments are submitted whenever necessary to reflect changes in Federal statute or regulation, or, material changes in State law, policy or program operation. Our experience is that a State Agency will amend a plan once every four years and that 12 will amend their plans annually.

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
State Plan for FC, ILP and AA	12	1	15	180

Estimated Total Annual Burden Hours: 180.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, 30 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: May 9, 2002.

Bob Sargis,

Reports Clearance, Officer.

[FR Doc. 02–12319 Filed 5–16–02; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2635]

ANDAs: Blend Uniformity Analysis; Withdrawal of Draft Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of a draft guidance that was issued on August 27, 1999.

FOR FURTHER INFORMATION CONTACT: Devinder S. Gill, Center for Drug Evaluation and Research (HFD–623), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–5848.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of August 27, 1999 (64 FR 46917), FDA announced the availability of a draft guidance for industry entitled ''ANDAs: Blend Uniformity Analysis.'' The draft guidance was intended to provide recommendations to sponsors of abbreviated new drug applications (ANDAs) on what information should be provided in an ANDA to support the demonstration and bioequivalence batches and to establish in-process acceptance criteria related to blend uniformity analysis (BUA) for the manufacture of some drug products. Written comments on the draft guidance were to be submitted by October 26, 1999.

After careful consideration of the comments received, FDA has decided to withdraw the draft guidance. The information and comments from the public raised scientific issues relating to the scope of the guidance and methodology for blend uniformity analysis in general, including the: (1) Adequacy of current blend sampling

techniques and (2) appropriateness of various test methods for assessing blend uniformity. The agency has decided that further research on BUA is needed. FDA is participating in research on BUA through the Product Quality Research Institute (PQRI). Based on the results of the research and recommendations submitted by PQRI, FDA will determine whether a new guidance on BUA will be issued.

An applicant or manufacturer must still comply with any applicable regulations regardless of the status of this guidance. For example, an application must include specifications and analytical methods to ensure the identity, strength, quality, purity, and bioavailability of the drug product (21 CFR 314.50(d)(1)(ii)(a)), and a manufacturer must monitor and validate the performance of processes that could be responsible for variability, including adequacy of mixing to ensure uniformity and homogeneity (21 CFR 211.110(a)(3)). An evaluation of uniformity of a blend may be necessary to fulfill such requirements.

Dated: May 6, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–12359 Filed 5–16–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1679]

Compliance Policy Guidance for FDA Staff and Industry on Blood Donor Classification Statement, Paid or Volunteer Donor; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Blood Donor Classification Statements, Paid or Volunteer Donor,'' dated May 7, 2002. The guidance document provides guidance to FDA staff and industry for determining when blood or blood components should be labeled with a ''paid donor'' or ''volunteer donor'' classification statement. The document is intended to assist industry in determining when a donor incentive is considered a monetary payment, and to assist FDA employees in inspecting blood centers. This guidance finalizes the document entitled ''Draft Compliance Policy Guidance for FDA Employees and Industry on Blood Donor Incentives,'' published in the **Federal Register** of January 16, 2001 (66 FR 3605).

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this compliance policy guidance to the Division of Compliance Policy (HFC–230), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist the office in processing your requests. You may fax your request to 301–827–0852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Tom M. Chin, Division of Compliance Policy (HFC–230), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0410.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a compliance policy guidance document entitled ''Blood Donor Classification Statements, Paid or Volunteer Donor,'' dated May 7, 2002. The guidance document provides information to industry and FDA employees regarding when a blood donor incentive would require the blood or blood component to be labeled with a ''paid donor'' or ''volunteer donor'' classification statement.

In the **Federal Register** of January 13, 1978 (43 FR 2142), FDA published a final rule requiring that blood and blood components intended for transfusion include a statement on the labels that indicated whether the products were collected from a paid or volunteer donor (§ 606.121(c)(5) (21 CFR 606.121(c)(5))). The regulation defines a ''paid donor'' as a person who receives monetary payment for blood donation (§ 606.121(c)(5)(i)). A volunteer donor is a person who does not receive monetary payment for blood donation (§ 606.121(c)(5)(ii)).

The requirement for a donor classification statement applies only to blood and blood components intended for transfusion. It does not apply to blood and blood components intended for further manufacturing, such as Source Plasma.

If the donor receives an incentive other than cash, the incentive must be evaluated to determine if it is readily convertible to cash. This guidance document provides FDA employees and industry with the factors that FDA uses to evaluate incentives, and provides some examples of incentives that the Center for Biologics Evaluation and Research has evaluated in the past.

This guidance finalizes the draft guidance entitled ''Draft Compliance Policy Guidance for FDA Employees and Industry on Blood Donor Incentives'' (66 FR 3605). The title of the document was changed to more accurately reflect its contents.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance document represents the agency's current thinking on blood donor classification statements. 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 and regulations.

III. Discussion of Comments

The agency received a number of comments on the draft compliance policy guidance (66 FR 3605). All of the comments were considered when preparing the final document.

Some of the comments requested further guidance on blood donor incentives that was outside of the scope of this document. FDA will consider issuing further guidance on the subject of blood donor incentives in the future.

IV. Comments

Interested persons may, at any time, submit written comments to the Dockets Management Branch (address above) regarding this guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the 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.

V. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/ora/compliance__ref/cpg/default.htm.