

Children and Family Services (State) for a hearing to contest the Administration for Children and Families' (ACF) disapproval of an amendment to the State's plan for implementing title IV-E of the Social Security Act (Foster Care and Adoption Assistance).

The basis for the disapproval is that the plan amendment alters the eligibility criteria for title IV-E Foster Care in a manner that is inconsistent with the criteria at section 472 of the Social Security Act (Act) (42 U.S.C. 672).

Section 472(a) requires that each state with an approved plan under title IV-E make foster care maintenance payments with respect to a child who has been removed from his or her home and placed in foster care pursuant to a voluntary placement agreement or court order, and who would have been eligible for benefits under the former Aid to Families with Dependent Children (AFDC) program at former title IV-A of the Act (as in effect on July 16, 1996) in the month in which the agreement was entered or court proceedings initiated, or within six months prior to such month, if the child had still been in the home from which the child was removed.

The State's plan amendment (Transmittal No. 03-4) would alter the eligibility requirements with respect to whether the child must have been eligible for AFDC in the home from which he or she was removed, consistent with the holding of the U.S. Court of Appeals for the Ninth Circuit in *Rosales v. Thompson*, 321 F.3d 835 (9th Cir. 2003). That case involved a child who was removed from his parent's home and placed informally with a grandparent who later became the child's foster care parent upon entry of the court order legally removing the child from the parent's home. The child would not have been eligible for AFDC payments while in the parent's home, but was eligible in the grandparent's home. The court found that the child was eligible for title IV-E Foster Care, based on the child's eligibility for AFDC while residing informally in the grandparent's home.

ACF has determined that the holding in *Rosales v. Thompson* misinterprets the Act and conflicts with Department regulations and policy, and has declined to apply it with respect to states outside the Ninth Circuit. ACF has determined that the child's eligibility for AFDC must be based on the home of the parent or other specified relative who was the child's legal guardian and from which the child is legally removed, and not on the home of a specified relative with whom the child resides informally after

the child has been physically removed from home of the child's parent or specified relative who was the child's legal guardian, but prior to the judicial determination or voluntary placement agreement legally removing the child from the home of the child's parent or other specified relative who was the child's legal guardian.

I have designated Donald F. Garrett, a member of the Departmental Appeals Board, as the presiding officer pursuant to 45 CFR 213.21. ACF and the State are now parties in this matter. 45 CFR 213.15(a). The parties have agreed that there are no disputed issues of fact, and that an in-person hearing is not necessary to resolve the State's request for reconsideration. Accordingly, the parties have agreed that the appeal be decided based on their written submissions.

A copy of this letter will appear as a notice in the **Federal Register** and any individual or group wishing to request recognition as a party will be entitled to file a petition pursuant to 45 CFR 213.15(b) with the Departmental Appeals Board within 15 days after that notice has been published. A copy of the petition should be served on each party of record at that time. The petition must explain how the issues to be considered have caused them injury and how their interest is within the zone of interests to be protected by the governing Federal statute. 45 CFR 213.15(b)(1). In addition, the petition must concisely state petitioner's interest in the proceeding, who will represent petitioner, and the issues on which petitioner wishes to participate. 45 CFR 213.15(b)(2). Additionally, if petitioner believes that there are disputed issues of fact which require an in-person hearing, petitioner should concisely specify the disputed issues of fact in the petition, and also state whether petitioner intends to present witnesses. Petitioners may also, within 15 days after this notice has been published, request extensions of the time for requesting participation for the purpose of obtaining and reviewing copies of the parties' written submissions.

Any party may, within 5 days of receipt of such petition, file comments thereon; the presiding officer will subsequently issue a ruling on whether and on what basis participation will be permitted.

Any interested person or organization wishing to participate as amicus curiae may also file a petition with the Board, which shall conform to the requirements at 45 CFR 213.15(c)(1). This petition, or a request for an extension of time to review the briefs, must be filed within 15 days after this

notice has been published, to permit the presiding officer an adequate opportunity to consider and rule upon it.

Upon the conclusion of proceedings in this matter, the presiding officer will issue a proposed decision. I will then issue the final decision of the Department. 45 CFR 213.22, 213.32.

Any further inquiries, submissions, or correspondence regarding this matter should be filed in an original and two copies with Mr. Garrett at the Departmental Appeals Board, Appellate Division, MS-6127, Room G-644, Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201. For convenience please refer to Board Docket No. A-04-82. Electronic inquiries, submissions, or correspondence may be submitted by sending electronic mail (e-mail) to Jeffrey Sacks, Departmental Appeals Board Staff Attorney, at jeffrey.sacks@hhs.gov. Submit comments as an ASCII file avoiding the use of special characters and any form of encryption. The Board also accepts comments and data on disks in Word, WordPerfect or ASCII file format. Identify all submissions by Board Docket No. A-04-82.

The record in this matter, including the parties' written submissions, is available for public inspection. Interested persons or organizations may contact Jeffrey Sacks, Board Staff Attorney, at 202-565-0123 (or at jeffrey.sacks@hhs.gov) to arrange for inspection and copying of the record. Each submission must include a statement that a copy of the submission has been sent to the other parties, identifying when and to whom the copy was sent. For convenience please refer to Board Docket No. A-04-82.

Dated: December 16, 2004.

Wade F. Horn,

Assistant Secretary for Children and Families.
[FR Doc. 05-1452 Filed 1-26-05; 8:45 am]

BILLING CODE 4184-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cellular, Tissue and Gene Therapies Advisory Committee (formerly the Biological Response Modifiers Advisory Committee); Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Cellular, Tissue and Gene Therapies Advisory Committee (formerly the Biological Response Modifiers Advisory Committee).

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 3, 2005, from 8 a.m. to approximately 5:15 p.m. and on March 4, 2005, from 8 a.m. to approximately 2:30 p.m.

Location: Quality Suites, 3 Research Court, Rockville, MD.

Contact Person: Gail Dapolito or Rosanna L. Harvey, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512389. Please call the Information Line for up-to-date information on this meeting.

Agenda: On March 3 and 4, 2005, the Committee will discuss cellular therapies for repair and regeneration of joint surfaces. The Committee will also receive the following updates: (1) On March 3, 2005, in the afternoon, updates of research programs in the Center for Biologics Evaluation and Research and the Center for Drug Evaluation and Research; (2) on March 4, 2005, in the morning, update on the FDA Critical Path Initiative.

Procedure: On March 3, 2005, from 8 a.m. to approximately 4:45 p.m. and on March 4, 2005, from 8 a.m. to approximately 2:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by February 23, 2005. Oral presentations from the public will be scheduled on March 3, 2005, between approximately 11 a.m. and 11:30 a.m. and on March 4, 2005, between approximately 8:45 a.m. and 9:15 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 23, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the

approximate time requested to make their presentation.

Closed Committee Deliberations: On March 3, 2005, from approximately 4:45 p.m. to 5:15 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The Committee will discuss research programs in the Center for Biologics Evaluation and Research and the Center for Drug Evaluation and Research.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Gail Dapolito at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 19, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05-1473 Filed 1-26-05; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0366]

From Concept to Consumer: Center for Biologics Evaluation and Research Working With Stakeholders on Scientific Opportunities for Facilitating Development of Vaccines, Blood and Blood Products, and Cellular, Tissue, and Gene Therapies; Public Workshop; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until January 27, 2006, the comment period for the notice of public workshop and request for comments published in the **Federal Register** of August 31, 2004 (69 FR 53077). FDA is reopening the comment period to allow interested persons additional time to submit comments and to receive any new information.

DATES: Submit written or electronic comments by January 27, 2006.

ADDRESSES: Submit written comments to the Division of Dockets Management (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:

Astrid Szeto, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 31, 2004 (69 FR 53077) (August 2004 notice), FDA announced a public workshop entitled "From Concept to Consumer: Center for Biologics Evaluation and Research Working With Stakeholders on Scientific Opportunities for Facilitating Development of Vaccines, Blood and Blood Products, and Cellular, Tissue, and Gene Therapies." The public workshop was held on October 7, 2004. The goal of the public workshop was to provide a forum for stakeholders to discuss opportunities for and potential approaches to the development of innovative scientific knowledge and tools to facilitate the development and availability of new biological products including vaccines, blood and blood products, and cellular, tissue, and gene therapies.

Interested persons were originally given until September 23, 2004, to comment on the topic of the workshop.

II. Request for Comments

Following publication of the August 2004 notice, FDA received several requests to allow interested persons additional time to comment. The requesters asserted that the time period of 23 days was insufficient to respond fully to FDA's specific requests for comments and to allow potential respondents to thoroughly evaluate and address pertinent issues.

III. How to Submit Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments> or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the