

SUMMARY: Notice is hereby given that ACYF will award grant funds without competition to the National Adoption Center, Inc. (NAC), Philadelphia, Pennsylvania. This grant is a sole source award which will support the operation of the National Adoption Information Exchange and the continued development, expansion and implementation of a national Internet-based photo-listing activity. This award is made noncompetitively after our review of a proposal submitted by the NAC.

Background

In 1983, the National Adoption Center (then doing business as the Adoption Center of Delaware Valley) received a competitive grant award for a field-initiated proposal to develop a computerized database of children freed for adoption and waiting placement from state child welfare agencies. This database activity became known as the National Adoption Exchange and had been authorized in law in 1978 with the passage of the Adoption Opportunities Act. Currently, children are entered into the database by caseworkers from 44 States, though all 50 States are members of the exchange system and may enter information on adoptable children into the database. Subsequent to the development of the database/exchange in the mid-1990s, NAC developed a small internet-based listing, with accompanying photographs, of some of the children, using privately generated funds and in-kind expert services from computer software corporations. Currently, this photo listing has expanded to include children from 43 State child welfare agencies.

In 1998, President Clinton announced an initiative to mount a national internet-based photo listing of children adoptable from public child welfare agencies. In FY 2000, the Congressional Conference Report Language included a reference to NAC by saying, "The conference agreement includes \$400,000 for the National Adoption Center to develop a national adoption photo listing service on the Internet." The Senate Report Language also referenced NAC by saying "The Committee recognizes that, under the Adoption and Safe Families Act, States are required to use all available resources to find homes for children. The Committee is aware that the National Adoption Center operates a multi-state, technology-based adoption clearinghouse to facilitate placement of needy children with adoptive parents. The Committee understands that the Department plans to implement a national adoption photo listing service on the Internet to help

increase the number of adoptions. The Committee supports the idea that a national web site could include all youngsters available in public adoptions and will increase the likelihood that children will find loving, stable homes. The National Adoption Center has been at the forefront of developing and implementing technology-based resources to help facilitate adoptions and could be instrumental in creating a national adoption web site."

Following our review of the proposal submitted by the NAC for these activities, this award is made noncompetitively. The NAC proposal presents a unique opportunity to produce important progress on a set of tasks of significant interest to the Department.

The project period will be for 24 months, beginning September 29, 2000 and ending September 30, 2001. The grantee will be awarded \$900,000 during the first twelve months of the project period. The grantee may, in the second twelve months of the project period, be awarded additional noncompetitive continuation funding of up to \$1.6 million, depending on the availability of funds, satisfactory performance by the grantee, and a determination that such continued funding would be in the best interest of the government.

Authority: This award will be made pursuant to the Adoption Opportunities: Title II of the Child Abuse Prevention and Treatment and Adoption Reform Act of 1978, as amended [42 U.S.C. 5111]. (CFDA 93.652).

FOR FURTHER INFORMATION CONTACT: Sally Flanzer, Children's Bureau, Administration on Children, Youth and Families, 330 C Street, SW, Room 2429, Washington, D.C. 20447; Telephone: (202) 205-8914.

Dated: September 20, 2000.

Patricia Montoya,
Commissioner, Administration on Children, Youth and Families.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00F-0812]

Bayer Co.; Filing of Food Additive Petition; Amendment; Withdrawal in Part

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is amending the filing notice for a food additive petition filed by Bayer Co. to clarify that the petitioner's request to amend the food additive regulations to provide for a more descriptive term in place of "inhibitor of yeast," for the safe use of dimethyl dicarbonate (DMDC) will also involve adding related limitations to 21 CFR 172.133. The agency is also announcing the withdrawal of the petitioner's additional request to amend the food additive regulations to provide for the safe use of DMDC in noncarbonated juice beverages containing up to and including 100 percent juice.

FOR FURTHER INFORMATION CONTACT: Martha D. Peiperl, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3077.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of March 7, 2000 (65 FR 12014), FDA announced that a food additive petition (FAP 0A4718) had been filed by Bayer Co., c/o McKenna & Cuneo LLP, 1900 K St. NW., Washington, DC 20006-1108. The petition proposed to amend the food additive regulations in § 172.133 *Dimethyl dicarbonate* (21 CFR 172.133) both to provide for the safe use of DMDC in noncarbonated juice beverages containing up to and including 100 percent juice and to provide for a more descriptive term in place of "inhibitor of yeast," for the safe use of DMDC.

Upon further review of the petition, FDA determined that, if granted, the requested amendment of § 172.133 to provide for a more descriptive term in place of "inhibitor of yeast" for the safe use of DMDC will also require adding related limitations to this regulation. Therefore, FDA is amending the filing notice of March 7, 2000, to indicate that this proposed amendment will involve adding related limitations to § 172.133.

The petitioner's additional request, to amend the food additive regulations to provide for the safe use of DMDC in noncarbonated juice beverages containing up to and including 100 percent juice, was converted to a food contact substance notice (FCN 0035), 21 U.S.C. 348(h)(5). This request to amend the food additive regulations was withdrawn from the petition as of the effective date of FCN 0035 (June 9, 2000).

The agency has determined under 21 CFR 25.30(I) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore,

neither an environmental assessment nor an environmental impact statement is required.

Dated: September 14, 2000.

Alan M. Rulis,

*Director, Office of Premarket Approval,
Center for Food Safety and Applied Nutrition.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration [HCFA-1145-NC]

Medicare and Medicaid Programs; Announcement of Additional Applications From Hospitals Requesting Waivers for Organ Procurement Service Areas

AGENCY: Health Care Financing
Administration (HCFA), HHS.

ACTION: Notice with comment period.

SUMMARY: This notice announces two additional applications that we have received from hospitals requesting waivers from entering into agreements with their designated organ procurement organizations (OPOs) in accordance with section 1138(a)(2) of the Social Security Act. This notice requests comments from OPOs and the general public for our consideration in determining whether we should grant these waivers.

DATES: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on November 27, 2000.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA-1145-NC, P.O. Box 8016, Baltimore, MD 21244-8016.

To ensure that mailed comments are received in time for us to consider them, please allow for possible delays in delivering them.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses: Room 443-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5-16-03, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA-1145-NC. Comments received

timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 443-G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690-7890).

FOR FURTHER INFORMATION CONTACT:

Mark A. Horney, (410) 786-4554.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1138(a)(1)(A)(iii) of the Social Security Act (the Act) provides that a hospital must notify the designated OPO (for the service area in which it is located), as defined under section 1138(a)(3)(B) of the Act, of potential organ donors. Under section 1138(a)(1)(C) of the Act, the hospital must have an agreement to identify potential donors only with that designated OPO.

Section 1138(a)(2) of the Act provides that the hospital may obtain a waiver from the Secretary of these requirements. A waiver allows the hospital to have an agreement with an OPO, other than the designated OPO, if the hospital meets conditions specified in section 1138(a)(2)(A) of the Act. In addition, the Secretary may review additional criteria described in section 1138(a)(2)(B) of the Act to evaluate a hospital's waiver.

Section 1138(a)(2)(A) further states that in granting a waiver, the Secretary must determine that the waiver—(1) Is expected to increase organ donations; and (2) will ensure equitable treatment of patients referred for transplants within the service area served by the designated OPO and within the service area served by the OPO with which the hospital seeks to enter into an agreement under the waiver. In making a waiver determination, section 1138(a)(2)(B) of the Act provides that the Secretary may consider, among other factors: (1) Cost effectiveness; (2) improvements in quality; (3) whether there has been any change in a hospital's designated OPO service area due to the changes made in definitions for metropolitan statistical areas (MSAs); and (4) the length and continuity of a hospital's relationship with an OPO other than the hospital's designated OPO. Under section 1138(a)(2)(D) of the Act, the Secretary is required to publish a notice of any waiver application within 30 days of receiving the application and offer interested parties an opportunity to

comment in writing within 60 days of the published notice.

The regulations at 42 CFR 486.316(d) provide that if we change the OPO designated for an area, hospitals located in that area must enter into agreements with the newly designated OPO or submit a request for a waiver within 30 days of notice of the change in designation. The criteria that the Secretary uses to evaluate the waiver in these cases are the same as those described above under sections 1138(a)(2)(A) and (B) of the Act and have been incorporated into the regulations at §§ 486.316(e) and (f). Section 486.316(g) further specifies that a hospital may continue to operate under its existing agreement with a now out-of-area OPO while we are processing the waiver request submitted in accordance with § 486.316(d).

II. Waiver Request Procedures

In October 1995, we issued a Program Memorandum (Transmittal No. A-95-11) that has been supplied to each hospital. This Program Memorandum detailed the waiver process and discussed the information that hospitals must provide in requesting a waiver. We indicated that upon receipt of the waiver requests, we would publish a **Federal Register** notice to solicit public comments, as required by section 1138(a)(2)(D) of the Act.

We will review the requests and comments received. During the review process, we may consult on an as-needed basis with the Public Health Service's Division of Transplantation, the United Network for Organ Sharing, and our regional offices. If necessary, we may request additional clarifying information from the applying hospital or others. We will then make a final determination on the waiver requests and notify the affected hospitals and OPOs.

III. Additional Hospital Waiver Requests

As allowed under § 486.316(e), each of the following two hospitals has requested a waiver to have an agreement with an alternative, out-of-area OPO. The listing includes the name of the facility, the city and State of the facility, the requested OPO, and the currently designated area OPO. This request is not a result of a governmental change; therefore, the exception under § 486.316(g) does not apply to these two hospitals. Moreover, these hospitals may not work with the requested OPOs rather than the designated OPOs until the completion of our review.