West, Aerospace Building, Washington, DC 20447–0002, E-mail: *OCS@LCGNET.COM,* Telephone: (800) 281–9519.

Grants Management Office Contact: Barbara Ziegler, Office of Grants Management, Division of Discretionary Grants, 370 L'Enfant Promenade, SW., 4th Floor West, Aerospace Building, Washington, DC 20447–0002, E-mail: *OCS@LCGNET.COM,* Telephone: (800) 281–9519.

General: Office of Community Services Operations Center, Compassion Capital Fund Demonstration Program, 1815 North Fort Meyer Drive, Suite 300, Arlington, VA 22209, Attention: Eduardo Hernandez, Telephone: 1–800–281–9519, E-mail: *OCS@LCGNET.COM.*

VIII. Other Information

Additional information about this program and its purpose can be located on the following Web sites: *http://www.acf.hhs.gov/programs/ccf/, http://www.acf.hhs.gov/programs/ocs/, http://www.acf.hhs.gov/programs/ccf.*

Dated: March 15, 2004.

Clarence Carter,

Director, Office of Community Services.

[FR Doc. 04–6204 Filed 3–18–04; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003E–0458]

Determination of Regulatory Review Period for Purposes of Patent Extension; VELCADE

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for VELCADE and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

ADDRESSES: Submit written comments and petitions 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: Claudia Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–453–6699.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product VELCADE bortezomib). VELCADE for Injection is indicated for the treatment of multiple myeloma patients who have received at least two prior therapies and have demonstrated disease progression on the last therapy. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for VELCADE (U.S. Patent No. 5,780,454) from Millenium Pharmaceuticals, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated November 18, 2003, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of VELCADE represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for VELCADE is 1,723 days. Of this time, 1,610 days occurred during the testing phase of the regulatory review period, while 113 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: August 26, 1998. The applicant claims August 22, 1998, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 26, 1998, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: January 21, 2003. FDA has verified the applicant's claim that the new drug application (NDA) for VELCADE (NDA 21–602) was initially submitted on January 21, 2003.

3. *The date the application was approved*: May 13, 2003. FDA has verified the applicant's claim that NDA 21–602 was approved on May 13, 2003.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 920 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by May 18, 2004. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by September 15, 2004. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information 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. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 17, 2004.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 04–6159 Filed 3–18–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration of Children and Families

Office of Refugee Resettlement

Proposed Notice of Allocations to States of FY 2004 Funds for Refugee Social Services

AGENCY: Office of Refugee Resettlement (ORR), ACF, HHS.

ACTION: Proposed notice of allocations to States of FY 2004 funds for refugee social services.

[CFDA No.: 93.566, Refugee Assistance—State Administered Programs]

SUMMARY: This notice establishes the proposed allocations to States of FY 2004 funds for refugee [1] social services under the Refugee Resettlement Program (RRP). In the final notice, amounts may be adjusted based upon final adjustments to FY 2002 and FY 2003 data in some States.

DATES: Comments on this Notice must be received by April 19, 2004.

FOR FURTHER INFORMATION CONTACT: Kathy Do, Division of Budget, Policy, and Data Analysis (BPDA), telephone: (202) 401–4579, e-mail: *kdo@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION:

[1] Eligibility for refugee social services include refugees, asylees, Cuban and Haitian entrants, certain Amerasians from Viet Nam who are admitted to the U.S. as immigrants, certain Amerasians from Viet Nam who are U.S. citizens, and victims of a severe form of trafficking who receive certification or eligibility letters from ORR. *See* 45 CFR 400.43 and ORR State Letter #01–13 on the Trafficking Victims Protection Act, dated May 3, 2001, as modified by ORR State Letter # 02–01, January 4, 2002.

Due to recent legislative changes, certain family members who are accompanying or following to join victims of severe forms of trafficking also are eligible for ORR-funded benefits and services. These individuals have been granted nonimmigrant visas under 8 U.S.C. 1101(a)(15)(T)(ii).

The term ''refugee,'' used in this notice for convenience, is intended to encompass such additional persons who are eligible to participate in refugee program services.

I. Amounts for Allocation

The Office of Refugee Resettlement (ORR) has available $152,217,586 in FY 2004 refugee social service funds. *See* Consolidated Appropriations Act, 2004, Pub. L. 108–199. This amount reflects a recission of 0.59 percent applied across the board to all line items.

The FY 2004 Conference Report (H.R. Rept. No. 108–401) reads as follows with respect to social service funds:

> The conference agreement appropriates $450,276,000 rather than the $461,853,000 as proposed by H.R. 2660 and $428,056,000 as proposed by the Senate. Within this amount, $153,121,000 is provided for social services as proposed in H.R. 2660. The Senate bill included $140,000,000 for this purpose.
>
> The agreement also includes $19,000,000 for increased support to communities with large concentrations of Cuban and Haitian refugees of varying ages whose cultural differences make assimilation especially difficult justifying a more intense level and longer duration of Federal assistance for healthcare and education.
>
> The conferees recognize the importance of continued educational support to schools with a significant proportion of refugee children, consistent with previous support to schools heavily impacted by large concentrations of refugees, and urge the Office of Refugee Resettlement to support these efforts should funding become available in the social services or other programs.

ORR intends to use the $ 152,217,586 appropriated for FY 2004 social services as follows:

- Approximately $79,000,000 will be allocated under the 3-year population formula, as set forth in this notice for the purpose of providing employment services and other needed services to refugees.
- Approximately $14,000,000 is expected to be awarded as new and continuation social service discretionary grants under new and prior year competitive grant announcements issued separately from this proposed notice.
- Approximately $19,000,000 is expected to be awarded to serve communities most heavily affected by recent Cuban and Haitian entrant and refugee arrivals. These funds will be awarded under a prior year separate announcement.
- Approximately $28,000,000 is expected to be awarded through discretionary grants for continuation of awards made in prior years.
- Up to $15,000,000 will be utilized to continue the awards for educational support to schools with a significant proportion of refugee children, consistent with previous support to schools heavily impacted by large concentrations of refugees. Of this amount, up to $6,500,000 in prior year funds may be used to augment the current budget authority of $8,500,000.
- Approximately $2,000,000 is expected to be awarded through contracts for an evaluation of the effectiveness of ORR's employment programs.

Refugee Social Service Funds

The FY 2004 population figures that have been used for this proposed formula social services allocation include refugees, Amerasians from Viet Nam, Cuban/Haitian entrants, Havana parolees, and victims of severe forms of trafficking. These population figures will be adjusted in the final allocation to reflect more accurate information on arrivals in 2003, secondary migration (including that of victims of severe forms of trafficking) and asylee data submitted by States. (See Section IV. Basis of Population Estimates).

The Director proposes allocating $79,728,843 to States on the basis of each State's proportion of the national population of refugees who have been in the U.S. three years or less as of October 1, 2003 (including a floor amount for States that have small refugee populations). Of the amount proposed to be awarded, approximately $6 million is expected to be awarded to Wilson/Fish Alternative Projects providing social services.

The use of the 3-year population base in the allocation formula is required by section 412(c)(1)(B) of the Immigration and Nationality Act (INA) which states that ''funds available for a fiscal year for grants and contracts [for social services] * * * shall be allocated among the States based on the total number of refugees (including children and adults) who arrived in the United States not more than 36 months before the beginning of such fiscal year and who are actually residing in each State (taking into account secondary migration) as of the beginning of the fiscal year.''

As established in the FY 1992 social services notice published in the **Federal Register** on August 29, 1991, section I, ''Allocation Amounts'' (56 FR 42745), a variable floor amount for States which have small refugee populations is calculated as follows: If the application of the regular allocation formula yields less than $100,000, then —

(1) a base amount of $75,000 is provided for a State with a population of 50 or fewer refugees who have been in the U.S. 3 years or less; and

(2) for a State with more than 50 refugees who have been in the U.S. 3 years or less: (a) a floor has been calculated consisting of $50,000 plus