achieving the goals and objectives of the program. Brief resumes of current and proposed staff, as well as position descriptions, should be included. Position descriptions must specifically describe the job as it relates to the proposed project.

2. Applicant must describe the staffing pattern that would be used to ensure that well-trained personnel would be assigned to each shift during the 24 hours per day, seven days per week operating period.

(e.) UPD Requirement for Organizational Profile

Provide information on the applicant organization(s) and cooperating partners such as organizational charts, financial statements, audit reports or statements from CPAs/Licensed Public Accountants, Employer Identification Numbers, names of bond carriers, contact persons and telephone numbers, child care licenses and other documentation of professional accreditation, information on compliance with Federal/State/local government standards, documentation of experience in the program area, and other pertinent information.

Any nonprofit organization submitting an application must submit proof of its nonprofit status in its application at the time of submission. The nonprofit agency can accomplish this by providing a copy of the applicant's listing in the Internal Revenue Service's (IRS) most recent list of tax-exempt organizations described in Section 501(c)(3) of the IRS code, or by providing a copy of the currently valid IRS tax exemption certificate, or by providing a copy of the articles of incorporation bearing the seal of the State in which the corporation or association is domiciled.

Evaluation Criteria for Organizational Profile (10 points)

1. Applicant must discuss staff and organizational experience in working with runaway and homeless youth populations. As required by the RHY Act, priority for funding will be given to organizations with experience in providing national telephone hotline services to runaway and homeless youth in a manner that is in concert with the evaluation criteria for the NCS competitive grant program. Applicant must document the services it provides to this specific target population and the length of time that the applicant has been involved in the provision of these services.

2. Applicant must provide a short description of the applicant agency's organization, the experience of the organization with youth development, youth issues and youth and family services, and the role of any other offices or organizations that will be directly involved in this effort. Organizational charts may be provided.

(f.) UPD Requirement for Budget and Budget Justification

Provide line item detail and detailed calculations for each budget object class identified on the Budget Information form. Detailed calculations must include estimation methods, quantities, unit costs, and other similar quantitative detail sufficient for the calculation to be duplicated. The detailed budget must also include a breakout by the funding sources identified in Block 15 of the SF–424.

Provide a narrative budget justification that describes how the categorical costs are derived. Discuss the necessity, reasonableness, and allocability of the proposed costs.

Evaluation Criterion for Budget and Budget Justification (10 Points)

1. Applicant must show that costs of the proposed project are reasonable and justified in terms of numbers of youth and families to be served, types and quantities of services to be provided and the anticipated results and benefits. Discussion should refer to the budget information presented on Standard Forms 424 and 424A and in the applicant's budget justification.

2. Applicant must describe the fiscal control and accounting procedures that will be used to ensure prudent use, proper disbursement and accurate accounting of funds received under this program announcement.

3. Applicant must describe its plan for maximizing the non-Federal share through private sector resources that will enhance the overall program.

Required Notification of the Single Point of Contact

This program is covered under Executive Order (E.O.) 12372, ''Intergovernmental Review of Federal Programs,'' and 45 CFR part 100, ''Intergovernmental Review of Department of Health and Human Services Programs and Activities.'' The order was issued with the desire to foster the intergovernmental partnership and strengthen federalism by relying on State and local processes for the coordination and review of proposed Federal financial assistance and direct Federal development. Under the Order, States may design their own processes for reviewing and commenting on proposed Federal assistance under covered programs and designate an entity to perform this function. The official list of those entities can be found at *http://www.whitehouse.gov/omb/grants/spoc.html* or by calling the ACYF Operations Center at 1–800–351–2293.

Applicants must submit any required material to the SPOCs as early as possible so that the program office can obtain and review SPOC comments as part of the award process. The applicant must submit all required materials, if any, to the SPOC and indicate the date of this submittal (or date of contact if no submittal is required) on the Standard Form 424, item 16a.

Under 45 CFR 100.8(a)(2), a SPOC has 60 days from the application deadline date to comment on proposed new awards. SPOCs are encouraged to eliminate the submission of routine endorsements as official recommendations. Additionally, SPOCS are requested to clearly differentiate between mere advisory comments and those official State process recommendations which they intend to trigger the ''accommodate or explain'' rule. When comments are submitted directly to ACYF, they must be addressed to: Department of Health and Human Services, Administration on Children, Youth and Families, Family and Youth Services Bureau, Room 2038, Mary Switzer Building, 330 C Street, SW., Washington, DC 20447, Attention: Dorothy Pittard.

Dated: September 17, 2001.

James A. Harrell,

Acting Commissioner, Administration on Children, Youth and Families.

[FR Doc. 01–23766 Filed 9–21–01; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01E–0029]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Trileptal 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 Commissioner 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 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: Claudia Grillo, Office of Regulatory Policy (HFD–007), Food and Drug Administration,5600 Fishers Lane, Rockville, MD 20857, 301–594–5645.

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 Commissioner 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 Trileptal (oxcarbazepine). Trileptal is indicated for use as monotherapy or adjunctive therapy in the treatment of partial seizures in adults with epilepsy, and as adjunctive therapy in the treatment of partial seizures in children ages 4 through 16 with epilepsy. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Trileptal (U.S. Patent No. 4,559,174) from Novartis, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 11, 2001, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Trileptal 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 Trileptal is 2,523 days. Of this time, 2,046 days occurred during the testing phase of the regulatory review period, while 477 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*: February 18, 1993. The applicant claims February 4, 1992, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was February 18, 1993, 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*: September 25, 1998. FDA has verified the applicant's claim that the new drug application (NDA) for Trileptal (NDA 21–014) was initially submitted on September 25, 1998.

3. *The date the application was approved*: January 14, 2000. FDA has verified the applicant's claim that NDA 21–014 was approved on January 14, 2000.

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 1,690 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Dockets Management Branch (address above) written or electronic comments and ask for a redetermination, by November 23, 2001. 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 March, 24, 2002. 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 Dockets Management Branch. Three copies of any 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 5, 2001.

Jane A. Axelrad,

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

[FR Doc. 01–23750 Filed 9–21–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Current Good Manufacturing Practice for Active Pharmaceutical Ingredients; Public Workshops

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshops.

SUMMARY: The Food and Drug Administration (FDA) is announcing a series of workshops to discuss the application of the International Conference on Harmonisation (ICH) guidance for industry entitled ''Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients,'' which will be announced in a future issue of the **Federal Register**. The workshops, which will be held in collaboration with the Parenteral Drug Association, the Pharmaceutical Research and Manufacturers of America, and the Generic Pharmaceutical Association, are intended to provide a regulatory perspective on current good manufacturing practices (CGMPs) for active pharmaceutical ingredients (APIs). The workshops are being scheduled to help ensure that all APIs meet the standards for quality and purity they purport or are represented to possess.

DATES: See table 1 in the **SUPPLEMENTARY INFORMATION** section of this document.

ADDRESSES: See table 1 in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Erik N. Henrikson, Center for Drug