the education and training needs of its partner organizations on an annual basis, to ensure that they have the information and materials they need to assist the beneficiaries they serve. *Form Number:* CMS–10257 (OMB# 0938-New); *Frequency:* Once; *Affected Public:* Not-for-profit institutions, State, Local and Tribal governments, Federal Government; *Number of Respondents:* 4,000; *Total Annual Responses:* 4,000; *Total Annual Hours:* 1,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *July 1, 2008:*

1. *Electronically.* You may submit your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, *Attention:* Document Identifier/OMB Control Number _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: April 24, 2008.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E8–9503 Filed 5–1–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Delegation of Authority

Notice is hereby given that I have delegated to the Associate Commissioner, Children's Bureau, Administration for Children, Youth and Families, the following authorities vested in me by the Assistant Secretary for Children and Families by memorandum dated February 16, 2007.

(a) Authorities Delegated.

1. Authority to administer the Child Welfare Services Program, including the State Grant Program, the Research and Demonstration Program and the Training program pursuant to Title IV–B of the Social Security Act, and as amended now and hereafter.

2. Authority to administer the Foster Care Program and Adoption Assistance programs including the Independent Living Initiative under Title IV–E of the Social Security Act, and as amended now and hereafter.

3. Authority to administer the provisions of the Child Abuse Prevention and Treatment Act, 42 U.S.C. 5101 *et seq.,* and as amended now and hereafter.

4. Authority to administer the provisions of the Adoption Opportunities Program under Title II of the Child Abuse Prevention and Treatment and Adoption Reform Act, 42 U.S.C. 5111–5115, and as amended now and hereafter.

5. Authorities and functions vested in the Secretary under the Organic Act of the Children's Bureau (Act of April 9, 1912) 42 U.S.C. 191, *et seq.*, and as amended now and hereafter.

6. Authorities that provide for the establishment of A National Adoption Information Clearinghouse under Section 9442 of the Omnibus Budget Reconciliation Act of 1986, 42 U.S.C. 679a, and as amended now and hereafter.

7. Authorities to administer the Abandoned Infants Assistance Act of 1988, 42 U.S.C. 670 note, and as amended now and hereafter.

8. Authority under Section 13711(a)(2) of the Omnibus Budget Reconciliation Act of 1993, Pub. L. 103–66, for the Family Preservation and Support Services program, subpart 2 of the Title IV–B, Child and Family Services, of the Social Security Act 42 U.S.C. 629, and as amended now and hereafter.

9. Authorities vested in the Secretary of Health and Human Services under Section 330F (other than Section 330F(a)(6)(C)) of the Public Health Service Act (42 U.S.C. 254c–6), as amended, titled ''Certain Services for Pregnant Women.''

(b) Limitations.

1. This delegation of authority shall be exercised under the Department's existing policies on delegations and regulations.

2. This delegation excludes the authority to submit reports to Congress and shall be exercised under financial and administrative requirements applicable to all Administration for Children and Families' authorities.

3. The approval or disapproval of grant applications and the making of grant awards require concurrence of the appropriate Grants Officer. The approval or disapproval of contract proposals and awards are subject to the requirements of the Federal Acquisition Regulations and requires the concurrence of the Contracting Officer.

4. This delegation of authority does not include the authority to sign and issue notices of grant awards for Children's Bureau programs.

5. This delegation of authority does not include the authority to appoint Central Office and Regional Office Grant Officers for the administration of Children's Bureau programs.

6. This delegation of authority does not include the authority to appoint Action Officials for Audit Resolution.

7. This delegation of authority does not include the authority to approve or disapprove State requests for Federal financial participation for the costs of automated data processing equipment and services that affect more than one HHS Operating Division.

8. This delegation of authority does not include the authority to conduct hearings.

9. This delegation of authority does not include the authority under section 429 of the Social Security Act.

10. This delegation of authority does not include the authority under section 439 of the Social Security Act, Grants for Programs for Mentoring Children of Prisoners.

11. Any redelegation shall be in writing and prompt notification must be provided to all affected managers, supervisors, and other personnel and requires the concurrence of the Deputy Assistant Secretary for Administration.

(c) Effective Date.

This delegation of authority is effective upon the date of signature.

(d) Effect on Existing Delegations.

As related to the authorities delegated herein, this delegation of authority supersedes all previous delegations of authority.

I hereby affirm and ratify any actions taken by the Associate Commissioner, Children's Bureau, Administration on Children, Youth and Families, which involved the exercise of the authorities delegated herein prior to the effective date of this delegation.

Dated: April 18, 2008,

Joan Ohl,

Commissioner, Administration for Children, Youth and Families.

[FR Doc. E8–9634 Filed 5–1–08; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–E–0282] (formerly Docket No. 2007E–0256)

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for TEKTURNA 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 which 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.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

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 human drug product 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 TEKTURNA (aliskiren hemifumarate). TEKTURNA is indicated for treatment of hypertension. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for TEKTURNA (U.S. Patent No. 5,559,111) from Novartis Corporation, 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 21, 2007, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of TEKTURNA 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 TEKTURNA is 2,023 days. Of this time, 1,637 days occurred during the testing phase of the regulatory review period, while 386 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 22, 2001. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on August 22, 2001.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act:* February 13, 2006. FDA has verified the applicant's claim that the new drug application (NDA) for TEKTURNA (NDA 21–985) was initially submitted on February 13, 2006.

3. *The date the application was approved:* March 5, 2007. FDA has verified the applicant's claim that NDA 21–985 was approved on March 5, 2007.

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 2,022 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 July 1, 2008. 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 October 29, 2008. 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.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

Dated: April 21, 2008.

Jane A. Axelrad,

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

[FR Doc. E8–9699 Filed 5–1–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Cardiac Contractility, Hypertrophy, and Failure Study