synonymous with American Indian/Alaska Native.

L. *Native American (NA)*—Broadly describes the people considered indigenous to North America.

M. *Native American Affairs Advisory Council (NAAAC)*—An internal agency work group to support the Assistant Secretary for Children and Families, the Commissioner of the Administration for Native Americans, and all ACF program and regional offices that provide services to Native Americans.

N. *Native Hawaiian*—Any individual whose ancestors were natives of the area, which consists of the Hawaiian Islands prior to 1778 (42 U.S.C. 3057k).

O. *Inter-Tribal Organization*—A nongovernmental body organized and operated to represent the interests of a group of individuals considered indigenous to North American countries. Organizations that represent the interests of individuals do not fall under the intergovernmental committee exemption to FACA found in 2 U.S.C. Sec 1534. Therefore, the Department is required to adhere to FACA if representatives of those organizations are included on advisory committees or workgroups.

P. *Non-Recognized Tribe*—Any Tribe with whom the Federal Government does not maintain a government-to-government relationship, and to which the Federal Government does not recognize a trust responsibility.

Q. *Policies that have Tribal Implications*—Refers to regulations, legislation, and other policy statements or actions that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

R. *Public Participation*—When the public is notified of a proposed or actual action, and is provided meaningful opportunities to participate in the policy development process.

S. *Reservation*—Lands reserved with the Federal Government for tribal use and are usually held in trust by the Federal Government or within certain defined boundaries.

T. *Self Government*—Government in which the people who are most directly affected by the decisions make decisions.

U. *Sovereignty*—The ultimate source of political power from which all specific political powers are derived.

V. *State Recognized Tribes*—Tribes that maintain a special relationship with the State government and whose lands and rights are usually recognized by the State. State recognized Tribes may or may not be Federally recognized.

W. *Substantial Direct Compliance Costs*—Those costs incurred directly from implementation of changes necessary to meet the requirements of a Federal regulation. Because of the large variation in Tribes, "substantial costs" is also variable by Indian Tribe. Each Indian Tribe and the Secretary shall mutually determine the level of costs that represent "substantial costs" in the context of the Indian Tribe's resource base.

X. *To the Extent Practicable and Permitted by Law*—Refers to situations where the opportunity for consultation is limited because of constraints of time, budget, legal authority, *etc.*

Y. *Treaty*—A legally binding and written agreement that affirms the government-to-government relationship between two or more nations.

Z. *Tribal Government*—An American Indian or Alaska Native Tribe, band, nation, pueblo, village or community that the Secretary of the Interior acknowledges to exist as an Indian Tribe pursuant to the Federally recognized Indian Tribe List Act of 1994, (25 U.S.C. 479a).

AA. *Tribal Officials*—Elected or duly appointed officials of Indian Tribes or authorized inter-tribal organizations.

BB. *Tribal Organization*—The recognized governing body of any Indian Tribe; any legally established organization of American Indians and Alaska Natives which is controlled, sanctioned, or chartered by such governing body or which is democratically elected by the adult members of the community to be served by such organization and which includes the maximum participation of Indian Tribe members in all phases of its activities (25 U.S.C. 450b).

CC. *Tribal Resolution*—A formal expression of the opinion or will of an official tribal governing body which is adopted by vote of the tribal governing body.

DD. *Tribal Self-Governance*—The governmental actions of Tribes exercising self-government and self-determination.

14. Acronyms

ACF Administration for Children and Families
AI/AN American Indian/Alaska Native
AI/AN/NA American Indian/Alaska Native/Native American
ANA Administration for Native Americans
BIA Bureau of Indian Affairs
Division Staff Division and/or Operating Division
EO Executive Order
FACA Federal Advisory Committee Act
FR **Federal Register**
HHS U.S. Department of Health and Human Services
NAAAC Native American Affairs Advisory Council
OPDIV Operating Divisions of HHS
SPOC Single Point of Contact
TFWG Tribal/Federal Workgroup
U.S. United States
U.S.C. United States Code

15. Policy Review

ACF shall review, and if necessary revise, its Tribal Consultation Policy no less than every 2 years. Should ACF determine that the policy requires revision, the Tribal/Federal Workgroup will be convened to develop the revisions.

16. Retention of Executive Branch Authorities

Nothing in this policy waives the Government's deliberative process privilege, including when the Department is specifically requested by Members of Congress to respond to or report on proposed legislation. The development of such responses and related policy documents is a part of the deliberative process by the Executive Branch and should remain confidential.

Nothing in the Policy creates a right of action against the Department for failure to comply with this Policy nor creates any right, substantive or procedural, enforceable at law by a party against the United States, its agencies, or any individual.

17. Effective Date

This policy is effective on the date of signature by the Assistant Secretary for Children and Families and shall apply to all ACF Program Offices.

[FR Doc. 2010–31465 Filed 12–15–10; 8:45 am]

BILLING CODE 4184–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2001–E–0027]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ANGIOMAX 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 electronic comments to *http://www.regulations.gov.* Submit written petitions along with three copies and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 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 approved for marketing the human drug product ANGIOMAX (bivalirudin). ANGIOMAX is indicated for use as an anticoagulant in patients with unstable angina undergoing percutaneous transluminal coronary angioplasty. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ANGIOMAX (U.S. Patent No. 5,196,404) from The Medicines Company, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated September 6, 2001, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period, that the approval of ANGIOMAX represented the first permitted commercial marketing or use of the product, and that the patent term restoration application was untimely within the meaning of 35 U.S.C. section 156(d)(1).

On August 3, 2010, in *The Medicines Company* v. *David Kappos et al.,* Civil Action No. 01:10-cv-286, the United States District Court for the Eastern District of Virginia, Alexandria Division, ordered the United States Patent and Trademark Office to consider The Medicines Company's patent term restoration application for ANGIOMAX to have been timely filed. 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 ANGIOMAX is 3,665 days. Of this time, 2,576 days occurred during the testing phase of the regulatory review period, while 1,089 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 FD&C Act) (21 U.S.C. 355(i)) became effective:* December 5, 1990. The applicant claims November 2, 1990, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was December 5, 1990, 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 FD&C Act:* December 23, 1997. FDA has verified the applicant's claim that the new drug application (NDA) for ANGIOMAX (NDA 20–873) was submitted on December 23, 1997.

3. *The date the application was approved:* December 15, 2000. FDA has verified the applicant's claim that NDA 20–873 was approved on December 15, 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 1,773 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**) either electronic or written comments and ask for a redetermination by February 14, 2011. 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 June 14, 2011. 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.

Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) electronic or written comments and written petitions. It is only necessary to send one set of comments. It is no longer necessary to send three copies of mailed comments. However, if you submit a written petition, you must submit three copies of the petition. Identify comments with the docket number found in brackets in the heading of this document.

Comments and petitions that have not been made publicly available on regulations.gov may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 22, 2010.

Jane A. Axelrad,

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

[FR Doc. 2010–31583 Filed 12–15–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0605]

Small Entity Compliance Guide: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary