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 USPTO 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 has approved for marketing the human drug product AKYNZEO (netupitant/palonosetron hydrochloride). AKYNZEO is indicated for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy including, but not limited to, highly emetogenic chemotherapy. Subsequent to this approval, the USPTO received a patent term restoration application for AKYNZEO (U.S. Patent No. 6,297,375) from Hoffmann-La Roche Inc., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 30, 2015, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of AKYNZEO represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for AKYNZEO is 1,858 days. Of this time, 1,479 days occurred during the testing phase of the regulatory review period, while 379 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 (FD&C Act) (21 U.S.C. 355(i)) became effective:* September 10, 2009. FDA has verified the applicant's claim that September 10, 2009, is the date the investigational new drug application (IND) became effective.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* September 27, 2013. The applicant claims September 25, 2013, as the date the new drug application (NDA) for AKYNZEO (NDA 205718) was initially submitted. However, FDA records indicate that NDA 205718 was submitted on September 27, 2013.

3. *The date the application was approved:* October 10, 2014. FDA has verified the applicant's claim that NDA 205718 was approved on October 10, 2014.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,118 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (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.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: February 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–02756 Filed 2–9–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Low Income Levels Used for Various Health Professions and Nursing Programs Authorized in Titles III, VII, and VIII of the Public Health Service Act

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HRSA is updating income levels used to identify a ''low income family'' for the purpose of determining eligibility for programs that provide health professions and nursing training to individuals from disadvantaged backgrounds. These various programs are authorized in Titles III, VII, and VIII of the Public Health Service Act.

SUPPLEMENTARY INFORMATION: HHS periodically publishes in the **Federal Register** low-income levels to be used by institutions receiving grants and cooperative agreements to determine eligibility for programs providing training for (1) disadvantaged individuals, (2) individuals from disadvantaged backgrounds, or (3) individuals from low-income families. Many health professions and nursing grant and cooperative agreement awardees use the low-income levels to determine whether potential program participants are from an economically disadvantaged background and would be eligible to participate in the program, as well as to determine the amount of funding the individual receives. Awards are generally made to accredited schools of medicine, osteopathic medicine, public health, dentistry, veterinary medicine, optometry, pharmacy, allied health, podiatric medicine, nursing, and chiropractic; public or private nonprofit schools which offer graduate programs in behavioral health and mental health practice; and other public or private nonprofit health or education entities to assist the disadvantaged to enter and graduate from health professions and nursing schools. Some programs provide for the repayment of health professions or nursing education loans for disadvantaged students.

A ''low-income family/household'' for programs included in Titles III, VII, and VIII of the Public Health Service Act is defined as having an annual income that does not exceed 200 percent of the Department's poverty guidelines. A family is a group of two or more

individuals related by birth, marriage, or adoption who live together.

Most HRSA programs use the income of a student's parent(s) to compute low income status. However, a ''household'' may potentially be only one person. Other HRSA programs, depending upon the legislative intent of the program, the programmatic purpose related to income level, as well as the age and circumstances of the participant, will apply these low income standards to the individual student to determine eligibility, as long as he or she is not listed as a dependent on the tax form of his or her parent(s). Each program announces the rationale and choice of methodology for determining low income levels in program guidance.

Low-income levels are adjusted annually based on HHS's poverty guidelines. HHS's poverty guidelines are based on poverty thresholds published by the U.S. Census Bureau, adjusted annually for changes in the Consumer Price Index. The income figures below have been updated to reflect HHS's 2018 poverty guidelines as published in 83 FR 2642 (January 18, 2018).

LOW INCOME LEVELS BASED ON THE 2018 POVERTY GUIDELINES FOR THE 48 CONTIGUOUS STATES AND THE DISTRICT OF COLUMBIA

Persons in family/household *	Income level **
1	$24,280
2	32,920
3	41,560
4	50,200
5	58,840
6	67,480
7	76,120
8	84,760

For families with more than 8 persons, add $8,640 for each additional person.

* Includes only dependents listed on federal income tax forms.

** Adjusted gross income for calendar year 2017.

LOW INCOME LEVELS BASED ON THE 2018 POVERTY GUIDELINES FOR ALASKA

Persons in family/household *	Income level **
1	$30,360
2	41,160
3	51,960
4	62,760
5	73,560
6	84,360
7	95,160
8	105,960

For families with more than 8 persons, add $10,800 for each additional person.

* Includes only dependents listed on federal income tax forms.

** Adjusted gross income for calendar year 2017.

LOW INCOME LEVELS BASED ON THE 2018 POVERTY GUIDELINES FOR HAWAII

Persons in family/household *	Income level **
1	$27,920
2	37,860
3	47,800
4	57,740
5	67,680
6	77,620
7	87,560
8	$97,500

For families with more than 8 persons, add $9,940 for each additional person.

* Includes only dependents listed on federal income tax forms.

** Adjusted gross income for calendar year 2017.

Separate poverty guidelines figures for Alaska and Hawaii reflect Office of Economic Opportunity administrative practice beginning in the 1966–1970 period since the U.S. Census Bureau poverty thresholds do not have separate figures for Alaska and Hawaii. The poverty guidelines are not defined for Puerto Rico or other outlying jurisdictions. Puerto Rico and other outlying jurisdictions must use the low-income levels table for the 48 contiguous states and the District of Columbia.

Dated: February 5, 2018.

George Sigounas,

Administrator.

[FR Doc. 2018–02707 Filed 2–9–18; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings of the NHLBI Special Emphasis Panel.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel for Development of Transcatheter Electrosurgical Devices.

Date: March 2, 2018.

Time: 1:30 p.m. to 3:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 7196, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Stephanie J. Webb, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Suite 7196, Bethesda, MD 20892, 301–827–7992, *stephanie.webb@nih.gov*.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel for Non-Surgical Interventional Cardiovascular Medical Devices.

Date: March 2, 2018.

Time: 12:00 p.m. to 1:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6701 Rockledge Drive, Suite 7196, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Stephanie J. Webb, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7196, Bethesda, MD 20892, 301–827–7992, *stephanie.webb@nih.gov*.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; NHLBI Single-Site CLTR Review.

Date: March 13, 2018.

Time: 8:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn—Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Chang Sook Kim, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7188, Bethesda, MD 20892–7924, 301–827–7940, *carolko@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: February 6, 2018.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–02717 Filed 2–9–18; 8:45 am]

BILLING CODE 4140–01–P