The Commissioner will grant a hearing if there exists a genuine and substantial issue of fact or if the Commissioner concludes that a hearing would otherwise be of public interest (§ 314.200(g)(6)). If a hearing is granted, it will be conducted according to the procedures provided in 21 CFR parts 10 through 16 (21 CFR 314.201).

Paper submissions under this notice of opportunity for a hearing must be filed in two copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, submissions may be seen in the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, and on the internet at https://www.regulations.gov. This notice is issued under section 505(c)(1)(B) of the FD&C Act, §§ 314.110(b)(3) and 314.200.

Dated: February 8, 2018.
Janet Woodcock,
Director, Center for Drug Evaluation and Research.

For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

For further information contact:
Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:
I. Background

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 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 FARYDAK (panobinostat). FARYDAK, in combination with bortezomib and dexamethasone, is indicated for the treatment of patients with multiple myeloma who have received at least 2 prior regimens, including bortezomib and an immunomodulatory agent. This indication is approved under accelerated approval based on progression free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. Subsequent to this approval, the USPTO received patent term restoration applications for FARYDAK (U.S. Patent Nos. 6,552,065; 6,833,384; and 7,067,551) from Novartis AG, and the USPTO requested FDA’s assistance in determining the patents’ eligibility for patent term restoration. In a letter dated October 15, 2015, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of FARYDAK 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 FARYDAK is 4,334 days. Of this time, 3,997 days occurred during the testing phase of the regulatory review period, while 337 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: April 15, 2003. The applicant claims April 15, 2002, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was April 15, 2003, which was the first date after receipt of the IND that the investigational studies were allowed to proceed.
2. The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act: March 24, 2014. FDA has verified the applicant’s claim that the new drug application (NDA) for FARYDAK (NDA 205353) was initially submitted on March 24, 2014.
3. The date the application was approved: February 23, 2015. FDA has verified the applicant’s claim that NDA 205353 was approved on February 23, 2015. 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 applications for patent extension, this applicant seeks 1,751 days or 5 years 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 6, 2018.

Leslie Kux,
Associate Commissioner for Policy.
[FR Doc. 2018–02688 Filed 2–12–18; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0417]

Request for Nominations on the National Mammography Quality Assurance Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any industry organizations interested in participating in the selection of nonvoting industry representatives to serve on the National Mammography Quality Assurance Advisory Committee in the Center for Devices and Radiological Health notify FDA in writing. FDA is also requesting nominations for a nonvoting industry representative to serve on the National Mammography Quality Assurance Advisory Committee. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for an upcoming vacancy effective with this notice.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to FDA by March 15, 2018 (see sections I and II of this document for further details). Concurrently, nomination materials for prospective candidates should be sent to FDA by March 15, 2018.