

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 biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological 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 biological 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 biologic product KADCYLA (ado-trastuzumab emtansine). KADCYLA is indicated as a single agent, for the treatment of patients with HER2-positive metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination. Subsequent to this approval, the USPTO received patent term restoration applications for KADCYLA (U.S. Patent Nos. 7,097,840 and 8,337,856) from Genentech, Inc., and the USPTO requested FDA's assistance in determining these patents' eligibility for patent term restoration. In a letter dated May 23, 2014, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of KADCYLA 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 KADCYLA is 2,594 days. Of this time, 2,414 days occurred during the testing phase of the regulatory review period, while 180 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 (21 U.S.C. 355(i)) became effective:* January 18, 2006. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on January 18, 2006.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* August 27, 2012. The applicant claims August 24, 2012, as the date the biologics license application (BLA) for KADCYLA (BLA 125427) was initially submitted. However, FDA records indicate that BLA 125427 was submitted on August 27, 2012.

3. *The date the application was approved:* February 22, 2013. FDA has verified the applicant's claim that BLA 125427 was approved on February 22, 2013.

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 1,277 or 60 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 ask for a redetermination (see **DATES**). 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. To meet its burden, the petition must be timely (see **DATES**) and 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.

Submit petitions electronically to <http://www.regulations.gov> at Docket No. FDA-2013-S-0610. Submit written petitions (two copies are required) to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Petitions that have not been made publicly available on <http://www.regulations.gov> may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-P-1898]

Determination That KYTRIL (Granisetron Hydrochloride) Tablets, Equivalent 1 Milligram and 2 Milligram Base, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that KYTRIL (granisetron hydrochloride) tablets, equivalent (EQ) 1 milligram (mg) and 2 mg base, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for KYTRIL (granisetron hydrochloride) tablets, EQ 1 mg and 2 mg base, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Daniel Orr, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6246, Silver Spring, MD 20993–0002, 240–402–0979.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the *listed drug*, which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the “Approved Drug Products With

Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

KYTRIL (granisetron hydrochloride) tablets, EQ 1 mg and 2 mg base, are the subject of NDA 020305, held by Hoffmann-La Roche, Inc., and initially approved on March 16, 1995. KYTRIL is indicated for the prevention of nausea and/or vomiting associated with initial and repeat courses of emetogenic cancer therapy, including high-dose cisplatin, and for the prevention and treatment of postoperative nausea and vomiting in adults.

On April 30, 2012, Hoffman-La Roche notified FDA that KYTRIL (granisetron hydrochloride) tablets, EQ 1 mg and 2 mg base, were being discontinued, and FDA moved the drug products to the "Discontinued Drug Product List" section of the Orange Book.

Kurt R. Karst, on behalf of Hyman, Phelps & McNamara, P.C., submitted a citizen petition dated May 27, 2015 (Docket No. FDA-2015-P-1898), under 21 CFR 10.30, requesting that the Agency determine whether KYTRIL (granisetron hydrochloride) tablets, EQ 1 mg and 2 mg base, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that KYTRIL (granisetron hydrochloride) tablets, EQ 1 mg and 2 mg base, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that KYTRIL (granisetron hydrochloride) tablets, EQ 1 mg and 2 mg base, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of KYTRIL (granisetron hydrochloride) tablets, EQ 1 mg and 2 mg base, from sale. We have also independently

evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that the products were not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list KYTRIL (granisetron hydrochloride) tablets, EQ 1 mg and 2 mg base, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to KYTRIL (granisetron hydrochloride) tablets, EQ 1 mg and 2 mg base, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: December 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Externally-Led Patient-Focused Drug Development Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the opportunity for externally-led patient-focused drug development meetings. The Patient-Focused Drug Development (PFDD) initiative is part of FDA's commitments under the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). The PFDD initiative aims to more systematically obtain the patient perspective on specific diseases and their treatments. FDA recognizes that there are many more disease areas than can be addressed in the planned FDA meetings under PDUFA V. To help expand the benefits of FDA's PFDD initiative, FDA welcomes patient organizations to identify and organize patient-focused collaborations to generate public input on other disease

areas, using the process established through Patient-Focused Drug Development as a model.

ADDRESSES: FDA recommends that patient organizations who are interested in conducting an externally-led PFDD meeting initially engage with FDA by submitting a letter of intent (LOI) to patientfocused@fda.hhs.gov. Submission details are outlined on FDA's Web site: <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm453856.htm>.

FOR FURTHER INFORMATION CONTACT:

Pujita Vaidya, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1144, Silver Spring, MD 20993-0002, 301-796-0684.

SUPPLEMENTARY INFORMATION: As part of its commitments under the Prescription Drug User Fee Act reauthorization of 2012, FDA has taken several steps to inform the benefit-risk assessments that inform CDER's regulatory decisions concerning new drugs. Among these efforts is the PFDD initiative that aims to more systematically obtain the patient perspective on specific diseases and their treatments. FDA has committed to obtaining the patient perspective on at least 20 disease areas during the course of PDUFA V. PFDD meetings give FDA an important opportunity to hear directly from patients, patient advocates, and caretakers about the symptoms that matter most to them; the impact the disease has on patients' daily lives; and patients' experiences with currently available treatments. The patient perspective is critical in helping FDA understand the context in which regulatory decisions are made for new drugs. This patient input can inform FDA's decisions and oversight both during drug development and during our review of a marketing application.

The Agency recognizes that there has been growing external interest in expanding efforts to gather patient input in support of drug development and evaluation. To help expand the benefits of FDA's PFDD initiative, FDA welcomes patient organizations to identify and organize patient-focused collaborations to generate public input on other disease areas, using the process established through Patient-Focused Drug Development as a model. An externally-led PFDD meeting and any resulting products (e.g., surveys or reports) will not be considered FDA-sponsored or FDA-endorsed, and FDA does not guarantee specific involvement in such meetings. However, FDA will be