

ONC's Web site, www.healthit.gov/FDASIA.

II. Request for Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: April 1, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-07658 Filed 4-4-14; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Docket No. FDA-2012-E-0490]

Determination of Regulatory Review Period for Purposes of Patent Extension; MELAFIND SYSTEM

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for MELAFIND SYSTEM 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 medical device.

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written petitions (two copies are required) and written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit petitions electronically to <http://www.regulations.gov> at Docket No. FDA-2013-S-0610.

FOR FURTHER INFORMATION CONTACT:

Beverly Friedman, Office of Management, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6257,

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 medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. 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 (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 medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device MELAFIND SYSTEM. MELAFIND SYSTEM is indicated for use on clinically atypical cutaneous pigmented lesions with one or more clinical or historical characteristics of melanoma, excluding those with a clinical diagnosis of melanoma or likely melanoma. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for MELAFIND SYSTEM (U.S. Patent No. 6,208,749) from MELA Sciences Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated August 10, 2012, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of MELAFIND SYSTEM represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that the

FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for MELAFIND SYSTEM is 3,837 days. Of this time, 2,961 days occurred during the testing phase of the regulatory review period, while 876 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(g)) involving this device became effective, or, if an investigational device exemption (IDE) was not required, but institutional review board (IRB) approval is required, under section 520(g)(3) of the FD&C Act, the IRB approval date:* May 2, 2001. The applicant claims there was no IDE submitted under section 520(g) of the FD&C Act and claims the date that IRB-required approval was effective was May 2, 2001. FDA concurs that no IDE was submitted and that the IRB approval action was enacted May 2, 2001, according to the certificate of approval substantiating IRB approval date provided in the application for patent term extension.

2. *The date an application was initially submitted with respect to the device under section 515 of the the FD&C Act (21 U.S.C. 360e):* June 9, 2009. FDA has verified the applicant's claim that the premarket approval application (PMA) for MELAFIND SYSTEM (PMA P090012) was initially submitted June 9, 2009.

3. *The date the application was approved:* November 1, 2011. FDA has verified the applicant's claim that PMA P090012 was approved on November 1, 2011.

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 2,355 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 June 6, 2014. 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 6, 2014. 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 or electronic petitions. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to <http://www.regulations.gov>, Docket No. FDA–2013–S–0610. Comments and 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: March 27, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–07657 Filed 4–4–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–P–1199]

Determination That SKELAXIN (Metaxalone) Tablets, 400 Milligrams, Was 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 the Agency) has determined that SKELAXIN (metaxalone) Tablets, 400 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for SKELAXIN (metaxalone) Tablets, 400 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT:

Na'im R. Moses, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 240–402–3990.

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.

SKELAXIN (metaxalone) Tablets, 400 mg, is the subject of NDA 13–217, held by King Pharmaceuticals, Inc., and initially approved on August 13, 1962. SKELAXIN (metaxalone) is indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomforts associated with acute, painful musculoskeletal conditions.

The 400-mg dosage strength is currently listed in the “Discontinued Drug Product List” section of the Orange Book. The applicant continues to manufacture and distribute an 800-mg strength tablet of this drug product.

CorePharma, LLC, submitted a citizen petition dated September 19, 2013 (Docket No. FDA–2013–P–1199), under 21 CFR 10.30, requesting that the Agency determine whether SKELAXIN (metaxalone) Tablets, 400 mg, was 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 SKELAXIN (metaxalone) Tablets, 400 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that SKELAXIN (metaxalone) Tablets, 400 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of SKELAXIN (metaxalone) Tablets, 400 mg, 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 product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list SKELAXIN (metaxalone) Tablets, 400 mg, 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 SKELAXIN (metaxalone) Tablets, 400 mg, 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: April 1, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–07659 Filed 4–4–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting 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 the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant