DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2011–E–0014, FDA–2010–E–0660, and FDA–2010–E–0659]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for PROLIA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human biological 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. 6284, 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 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 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 biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human biological product PROLIA (denosumab). PROLIA is indicated for treatment of postmenopausal women with osteoporosis at high risk for fracture. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for PROLIA (U.S. Patent Nos. 6,740,522; 7,097,834; and 7,411,050) from Amgen, Inc., and the Patent and Trademark Office requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated April 27, 2011, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of PROLIA represented the first permitted commercial marketing or use of the product. 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 PROLIA is 3,269 days. Of this time, 2,739 days occurred during the testing phase of the regulatory review period, while 530 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:* June 21, 2001. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on June 21, 2001.

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):* December 19, 2008. FDA has verified the applicant's claim that the biologics license application (BLA) for PROLIA (BLA125320) was submitted on December 19, 2008.

3. *The date the application was approved:* June 1, 2010. FDA has verified the applicant's claim that BLA125320 was approved on June 1, 2010.

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 applications for patent extension, this applicant seeks 1,365 days; 952 days; and 595 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 July 6, 2012. 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 November 5, 2012. 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. However, if you submit a written petition, you must submit three copies of the petition. Identify comments with the docket numbers found in brackets in the heading of this document.

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: April 16, 2012.

Jane A. Axelrad,

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

[FR Doc. 2012–10959 Filed 5–4–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Food and Drug Administration/ International Society for Pharmaceutical Engineering Cosponsorship Educational Workshop: Redefining the 'C' in CGMP: Creating, Implementing, and Sustaining a Culture of Compliance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) Center for Drug Evaluation and Research, in cosponsorship with the International Society for Pharmaceutical Engineering (ISPE), is planning a multiday, educational public workshop entitled ''Redefining the 'C' in CGMP: Creating, Implementing, and Sustaining a Culture of Compliance.''

DATES: *Date and Time:* The public workshop will be held on June 4, 2012, 9 a.m. to 5 p.m. and June 5, 2012, 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Renaissance Baltimore Harborplace Hotel, 202 E. Pratt St., Baltimore, MD 21202, 1–800–535–1201.

Contact Persons: FDA Contact: Rhonda Hill, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4341, Silver Spring, MD 20993, 301–796–3267, *rhonda.hill@fda.hhs.gov.*

ISPE Contact: Julianne Rill, Continuing Education Program Manager, 600 N. Westshore Blvd., Suite 900, Tampa, FL 33609; Web site: *http://www.ispe.org/2012-gmp-conference;* email: *jrill@ispe.org.* (FDA has verified the Web site address in this announcement but we are not responsible for any subsequent changes to the Web site in this announcement after this document publishes in the **Federal Register.**)

Accommodations: Attendees are responsible for their own accommodations. Please mention ISPE/FDA Conference to receive the hotel room rate of $195.00 plus applicable taxes (available until May 7, 2012, or until the ISPE room block is filled).

If you need special accommodations due to a disability, please contact ISPE (see *Contact Persons*) at least 7 days in advance of the meeting.

Registration: The ISPE registration fees cover the cost of facilities, materials, and refreshments. Seats are limited; please submit your registration as soon as possible. Workshop space will be filled in order of receipt of registration. Those accepted for the workshop will receive confirmation. Registration will close after the workshop is filled.

COST OF REGISTRATION

ISPE member	$1,695
ISPE nonmember (includes membership).	2,035
Federal Government	750
FDA Planning Committee members and invited speakers.	Fee waived.

Please visit ISPE's Web site to confirm the prevailing registration fees.

To register, please submit a registration form with your name, affiliation, mailing address, telephone, fax number, and email, along with a check or money order payable to ''ISPE.'' To register via the Internet, go to *http://www.ispe.org/2012-gmp-conference.* The registrar will accept payment by major credit card (Visa/MasterCard/AMEX only). For more information on the meeting registration, or for questions on the workshop, contact ISPE (see *Contact Persons*).

SUPPLEMENTARY INFORMATION: The workshop helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health. The workshop will provide those engaged in FDA-regulated drug manufacturing operations with information on a number of topics concerning FDA requirements and expectations related to current good manufacturing practice (CGMP). The joint public workshop offers the opportunity for participants to join FDA representatives and industry experts in face-to-face dialogues. Each year, FDA speakers provide updates on current efforts affecting the development of global regulatory strategies, while industry professionals from some of today's leading pharmaceutical companies present case studies on how they employ strategies to manufacture high quality drugs in their daily processes. Through a series of sessions and meetings, the conference will provide participants with the opportunity to hear directly from FDA experts and representatives of global regulatory authorities on best practices. Topics for discussion include the following: (1) The Business Case For Change; (2) Quality Risk Management—When, What, and How; (3) Sustaining Compliance Consistency Throughout Your Company and Supplier Network; (4) IT Strategies—Cloud Computing, RFID, and Beyond; (5) The Future of Drug Manufacturing. To help ensure the quality of FDA regulated products, the workshop helps to achieve objectives set forth in section 406 of the FDA Modernization Act of 1997 (Pub. L. 105–115), which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), as outreach activities by Government Agencies to small businesses.

Dated: May 1, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–10894 Filed 5–4–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Educational Forum on Medical Device Reporting, Complaint Files, and Recalls, Corrections, and Removals; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Southwest Region (SWR), Dallas District Office (DALDO), in collaboration with the FDA Medical Device Industry Coalition (FMDIC), is announcing a public workshop entitled ''Educational Forum on Medical Device Reporting, Complaint Files, and Recalls, Corrections, and Removals.'' The purpose of the public workshop is to provide information about FDA's Medical Device Quality Systems Regulation (QSR) to the regulated industry, particularly small businesses.

DATES: *Date and Time:* The public workshop will be held on June 15, 2012, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Renaissance Dallas Hotel, 2222 Stemmons Freeway, Dallas, TX 75207. Directions and lodging information are available at the FMDIC Web site at *http://www.fmdic.org/.*

Contact Person: David Arvelo, Food and Drug Administration, 4040 North Central Expressway, Suite 900, Dallas, TX 75204, 214–253–4952, FAX: 214–253–4970, email *david.arvelo@fda.hhs.gov.*

Registration: FMDIC has a $250 early registration fee. Discounts for full-time students and government employees with valid identification are available. Early registration ends June 1, 2012. Registration is $300 thereafter. For more information on fees and/or to register online, please visit *http://www.fmdic.org/.* As an alternative, you may send registration information including name, title, firm name, address, telephone and fax numbers, and email, along with a check or money order for the appropriate amount payable to the FMDIC, to FMDIC Registrar, 4447 N. Central Expressway, Suite 110 PMB197, Dallas, TX 75205.