Filing Information

As a courtesy, we are making information related to Sunset proceedings, including copies of the pertinent statute and Department’s regulations, the Department schedule for Sunset Reviews, a listing of past revocations and continuations, and current service lists, available to the public on the Department’s Internet Web site at the following address: "http://ia.ita.doc.gov/sunset/". All submissions in these Sunset Reviews must be filed in accordance with the Department’s regulations regarding format, translation, service, and certification of documents. These rules can be found at 19 CFR 351.303. Pursuant to 19 CFR 351.103(d), the Department will maintain and make available a service list for these proceedings. To facilitate the timely preparation of the service list(s), it is requested that those seeking recognition as interested parties to a proceeding contact the Department in writing within 10 days of the publication of the Notice of Initiation.

Because deadlines in Sunset Reviews can be very short, we urge interested parties to apply for access to proprietary information under administrative protective order (“APO”) immediately following publication in the Federal Register of this notice of initiation by filing a notice of intent to participate. The Department’s regulations on submission of proprietary information and eligibility to receive access to business proprietary information under APO can be found at 19 CFR 351.304–306.

Information Required From Interested Parties

Domestic interested parties defined in section 771(9)(C), (D), (E), (F), and (G) of the Act and 19 CFR 351.102(b) wishing to participate in a Sunset Review must respond not later than 15 days after the date of publication in the Federal Register of this notice of initiation by filing a notice of intent to participate. The required contents of the notice of intent to participate are set forth at 19 CFR 351.218(d)(1)(ii). In accordance with the Department’s regulations, if we do not receive a notice of intent to participate from at least one domestic interested party by the 15-day deadline, the Department will automatically revoke the order without further review. See 19 CFR 351.218(d)(1)(iii).

If we receive an order-specific notice of intent to participate from a domestic interested party, the Department’s regulations provide that all parties wishing to participate in the Sunset Review must file complete substantive responses not later than 30 days after the date of publication in the Federal Register of this notice of initiation. The required contents of a substantive response, on an order-specific basis, are set forth at 19 CFR 351.218(d)(3). Note that certain information requirements differ for respondent and domestic parties. Also, note that the Department’s information requirements are distinct from the Commission’s information requirements. Please consult the Department’s regulations for information regarding the Department’s conduct of Sunset Reviews.1 Please consult the Department’s regulations at 19 CFR part 351 for definitions of terms and for other general information concerning antidumping and countervailing duty proceedings at the Department.

This notice of initiation is being published in accordance with section 751(c) of the Act and 19 CFR 351.218 (c).

Dated: January 25, 2011.

Christian Marsh
Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2011–2197 Filed 1–31–11; 8:45 am]

BILLING CODE 3510–05–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO–P–2011–0001]

Grant of Interim Extension of the Term of U.S. Patent No. 4,971,802; MIFAMURTIDE


ACTION: Notice of interim patent term extension.


FOR FURTHER INFORMATION CONTACT: Raul Tamayo by telephone at (571) 272–7728; by mail marked to his attention and addressed to the Commissioner for Patents, Mail Stop Hatch–Waxman PTE, P.O. Box 1450, Alexandria, VA 22313–1450; by fax marked to his attention at (571) 273–7728, or by e-mail to Raul.Tamayo@uspto.gov.

SUPPLEMENTARY INFORMATION: Section 156 of Title 35, United States Code, generally provides that the term of a patent may be extended for a period of up to five years if the patent claims a product, or a method of making or using a product, that has been subject to certain defined regulatory review, and that the patent may be extended for interims periods of up to a year if the regulatory review is anticipated to extend beyond the expiration date of the patent.

On September 30, 2010, IDM Pharma, agent/licensee of patent owner Novartis, timely filed an application under 35 U.S.C. 156(d)(5) for a fourth interim extension of the term of U.S. Patent No. 4,971,802. Claims of the patent cover muramyl tripeptide phosphatidyl ethanolamine, which is labeled as the active ingredient in the human drug product Mifamurtide. The application indicates, and the Food and Drug Administration has confirmed, that a New Drug Application for the human drug product Mifamurtide has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that, except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. 156, and that the patent should be extended for an additional year as required by 35 U.S.C. 156(d)(5)(B). Because it is apparent that the regulatory review period will continue beyond the extended expiration date of the patent (November 20, 2010), interim extension of the patent term under 35 U.S.C. 156(d)(5) is appropriate.

A fourth interim extension under 35 U.S.C. 156(d)(5) of the term of U.S. Patent No. 4,971,802 was granted for a period of one year from the extended...
CONSUMER PRODUCT SAFETY COMMISSION

Notice of Stay of Enforcement of Testing and Certification Pertaining to Youth All-Terrain Vehicles

AGENCY: Consumer Product Safety Commission.

ACTION: Stay of enforcement.

SUMMARY: The Consumer Product Safety Commission (“CPSC,” “Commission,” or “we”) is announcing its decision to stay enforcement of the testing of youth all-terrain vehicles (“ATVs”) by third party conformity assessment bodies, subject to conditions, until November 27, 2011.

DATES: This stay of enforcement is effective on February 1, 2011.

FOR FURTHER INFORMATION CONTACT: Elizabeth Leland, Project Manager, Directorate for Economic Analysis, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, Maryland 20814; e-mail eleeland@cpsc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 14(a)(3)(B)(vi) of the Consumer Product Safety Act (“CPSA”), as added by section 102(a)(2) of the Consumer Product Safety Improvement Act of 2008 (“CPSIA”), Public Law 110–314, directs the CPSC to establish and publish a notice of requirements for accreditation of third party conformity assessment bodies to assess children’s products for conformity with “other children’s product safety rules.” Section 14(f)(1) of the CPSA defines “children’s product safety rule” as “a consumer product safety rule under [the CPSA] or similar rule, regulation, standard, or ban under any other Act enforced by the Commission, including a rule declaring a consumer product to be a banned hazardous product or substance.” Under section 14(a)(3)(A) of the CPSA, 15 U.S.C. 2063(a)(3)(A), each manufacturer (including an importer) or private labeler of products subject to those regulations must have products that are manufactured more than 90 days after the establishment and Federal Register publication of a notice of the requirements for accreditation tested by a third party conformity assessment body accredited to do so, and must issue a certificate of compliance with the applicable regulations based on that testing. Pursuant to section 14(a)(3)(F) of the CPSA, the Commission may extend the 90-day period by not more than 60 days if the Commission determines that an insufficient number of third party conformity assessment bodies have been accredited to permit certification for a children’s product safety rule. Irrespective of certification, the product in question must comply with applicable CPSC requirements (see, e.g., section 14(h) of the CPSA, as added by section 102(b)(1) of the CPSIA).

In the Federal Register of August 27, 2010 (75 FR 52616), we published a notice of requirements that provided the criteria and process for Commission acceptance of accreditation of third party conformity assessment bodies for testing of ATVs designed or intended primarily for children 12 years of age or younger. The notice of requirements stated that, for youth ATVs manufactured after November 26, 2010, the manufacturer “must issue a certificate of compliance with 16 CFR part 1420 based on” testing performed by a third party conformity assessment body (75 FR 52618). The notice also asked for comments to be received by September 27, 2010.

In response to the notice of requirements, the Specialty Vehicle Institute of America (“SVIA”) filed a comment that included a request that the Commission extend by 60 days the date by which manufacturers must begin testing and certification of youth ATVs. Among the reasons given for the extension, were the complexity of 16 CFR part 1420 and the fact that no third party conformity assessment bodies have been accredited by an accrediting body that is a signatory to the International Laboratory Accreditation Cooperation-Mutual Recognition Arrangement (ILAC–MRA), a prerequisite for such conformity assessment bodies to be accepted by the CPSC.

On November 17, 2010, the SVIA filed a “Petition for Extension and Stay of Enforcement for Third Party Testing for Certain All-Terrain Vehicles.” The petition requested a 60-day extension of the date by which manufacturers must begin testing and certification of youth ATVs, stating that no third party conformity assessment bodies have been accredited by the CPSC to test for conformity with 16 CFR part 1420. The SVIA contended it is unlikely that a sufficient number of accredited third party conformity assessment bodies will exist by the end of the requested 60-day extension. As a result, the SVIA also requested that the Commission consider additional forms of relief, such as a further stay of enforcement of these requirements for one year (to November 27, 2011).

In response, in the Federal Register of December 9, 2010 (75 FR 76708), the Consumer Product Safety Commission announced that we would extend the date of testing and certification of youth ATVs until January 25, 2011. We acknowledged that we were “not aware of any third party conformity assessment bodies that have the requisite accreditation by an ILAC–MRA signatory to test for conformity to 16 CFR part 1420 and so we were granting the request for a 60-day extension (75 FR at 76709). However, with respect to the SVIA’s request for a one-year stay of enforcement, we decided to seek public comment and asked very specific questions:

(1) What efforts have been made by ATV manufacturers or others to obtain tests of youth ATVs by third party conformity assessment bodies and to encourage third party conformity assessment bodies to become accredited to do so?

(2) What is the status of the efforts of third party conformity assessment bodies to become accredited to test youth ATVs, and how long will it take to obtain such accreditation?

(3) What barriers currently exist to gaining accreditation that is specifically related to youth ATVs?

(4) How are ATV manufacturers currently demonstrating compliance with the ANSI/SVIA–1–2007 standard? What ATV manufacturers are currently doing in-house testing of their ATVs for conformance to the standard? What steps, if any, have these manufacturers taken to have their existing in-house testing facilities become accredited third party conformity assessment bodies?

(5) What third party testing facilities are capable of testing youth ATVs to the ANSI/SVIA–2007–1 standard?

II. Comments

We received more than 400 comments. Most comments were form letters that requested a stay of enforcement until November 27, 2011, because “the industry states that it will be unlikely enough labs will be online by the new January 25, 2011 deadline.” Most form letters were submitted by consumers, some of whom are members of the American Motorcyclist Association (“AMA”) and the All Terrain Vehicle Association (“ATVA”); the remaining form letters were submitted by rider associations, dealers,