DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Seafood Inspection and Certification Requirements

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements, and to minimize the public’s reporting burden. Public comments were previously requested via the Federal Register on May 25, 2021, during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: National Oceanic & Atmospheric Administration (NOAA), Commerce.

Title: Seafood Inspection and Certification Requirements.

OMB Control Number: 0648–0266.

Form Number(s): 89–800, 89–814, 89–891.

Type of Request: Regular submission (extension of a current information collection).

Number of Respondents: 1,012.

Average Hours per Response: Contract Completion, 5 minutes; Request for Service, 5 minutes; Label Approval, 1 hour; Appeals, 30 minutes; HACCP application new respondents, 60 hours; HACCP application current respondents, 40 hours.

Total Annual Burden Hours: 23,089.

Needs and Uses: This request is for the revision and extension of a current information collection.

The National Marine Fisheries Service (NMFS) operates the fee-for-service Seafood Inspection Program (SIP) under the authorities of the Agricultural Marketing Act of 1946, as amended, the Fish and Wildlife Act of 1956, and the Reorganization Plan No. 4 of 1970. The regulations for the SIP are contained in 50 CFR part 260. The SIP offers inspection, grading and certification services, including the use of official grade marks and statements which indicate that specific products have been federally inspected. The SIP is the only Federal entity which establishes quality grade standards for seafood marketed in the United States, and is the competent authority for the United States for issuing export health and catch certificates for seafood and certain other marine ingredients. Qualified participants are permitted to use SIP’s official grade marks and statements on their products to facilitate the domestic and global trade of fishery products and other marine ingredients. Participation in the SIP is open to all segments of the seafood industry, from harvesters and growers to retailers. When inspection service is desired, participants are required to submit specific information pertaining to the type of service needed (§ 260.15). This includes the type of products to be inspected, the quantity, the location of the product, and the date when the inspection is needed.

Customers complete the NOAA Form 89–814 Request for Inspection Services and submit it to their local inspection office via email or over the phone. There are also application requirements (i.e., a letter from the participant) if there is an appeal on previous service results (§ 260.36). Participants requesting regular inspection services on a contractual basis submit a contract using the NOAA Form 89–800 (§ 260.96). Any changes to the contract require a contract amendment, using the same form. When export or certain other forms of certification is desired, applicants are required to submit specific information regarding the consignment and the type of documents required, including details about the product, the shipper and the destination of the consignment, through an online portal system.

In July 1992, NMFS announced new inspection services, which were fully based on guidelines recommended by the National Academy of Sciences, known as Hazard Analysis Critical Control Point (HACCP). The information collection requirements fall under § 260.15 of the regulations. These guidelines require that a facility’s quality control system have a written plan of the operation, identification of control points with acceptance criteria and a corrective action plan, as well as personnel identified with responsibility for oversight of the system.

Affected Public: Business or other for-profit organizations; Not-for-profit institutions; State, Local, or Tribal government.

Frequency: On occasion.

Respondent’s Obligation: Required to obtain or maintain benefits.

Legal Authority: 7 U.S.C. 1621 et seq.

This information collection request may be viewed at www.reginfo.gov. Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function and entering either the title of the collection or the OMB Control Number 0648–0266.

Sheleen Dumas,
Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

Alexa Cole,
Director, Office of International Affairs and Seafood Inspection, National Marine Fisheries Service.

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DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO–P–2021–0052]

Grant of Interim Extension of the Term of U.S. Patent No. 7,199,162; GRAFAPEX™ (dihydroxybusulfan)

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of interim patent term extension.


FOR FURTHER INFORMATION CONTACT: Raul Tamayo, Senior Legal Advisor, Office of Patent Legal Administration, by telephone at 571–272–7728 or by email to raul.tamayo@uspto.gov.

SUPPLEMENTARY INFORMATION: 35 U.S.C. 156 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. 35 U.S.C. 156(b)(3) generally provides that the term of such a patent may be extended for no more than five interim periods of up to one year each, if the...
approval phase of the regulatory review period is reasonably expected to extend beyond the expiration date of the patent.

On September 23, 2021, Medac Gesellschaft fur Klinische Spezialpraparate mbH, the owner of record of the ‘162 patent, timely filed an application under 35 U.S.C. 156(d)(5) for a first interim extension of the term of the ‘162 patent. The ‘162 patent claims a method of using the human drug product known by the tradename GRAFAPEX™ (dihydroxybusulfan). The application for interim patent term extension indicates that a regulatory review period (RRP) as described in 35 U.S.C. 156(g)(1)(B)(ii) began for GRAFAPEX™ (dihydroxybusulfan) and is ongoing before the Food and Drug Administration for permission to market and use the product commercially.

Review of the interim patent term extension application indicates that, except for permission to market or use the product commercially, the ‘162 patent would be eligible for an extension of the patent term under 35 U.S.C. 156. Because it is apparent that the RRP will continue beyond the original expiration date of the ‘162 patent, i.e., October 12, 2021, interim extension of the patent term under 35 U.S.C. 156(d)(5) is appropriate.

A first interim extension under 35 U.S.C. 156(d)(5) of the term of U.S. Patent No. 7,199,162 is granted for a period of one year from the original expiration date of the ‘162 patent.

Robert Bahr,
Deputy Commissioner for Patents, United States Patent and Trademark Office.

SUPPLEMENTARY INFORMATION: 35 U.S.C. 156 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. 35 U.S.C. 156(d)(5) generally provides that the term of such a patent may be extended for no more than five interim periods of up to one year each, if the approval phase of the regulatory review period is reasonably expected to extend beyond the expiration date of the patent.

On August 25, 2021, TVAX Biomedical I, LLC, the owner of record of the ‘699 patent, timely filed an application under 35 U.S.C. 156(d)(5) for a third interim extension of the term of the ‘699 patent. The ‘699 patent claims a method of using a veterinary biological product in the cancer immunotherapy treatment known by the tradename EC1® (ELIAS Cancer Immunotherapy). The application for interim patent term extension indicates that an application for a license for the veterinary biological product was submitted under the Virus-Serum-Toxin Act and is currently undergoing regulatory review by the United States Department of Agriculture, Center for Veterinary Biologics.

Review of the interim patent term extension application indicates that, except for permission to market or use the product commercially, the ‘699 patent would be eligible for an extension of the patent term under 35 U.S.C. 156. Because it appears the approval phase of the regulatory review period will continue beyond the extended expiration date of the ‘699 patent, i.e., October 5, 2021, further interim extension of the patent term under 35 U.S.C. 156(d)(5) is appropriate.

A third interim extension under 35 U.S.C. 156(d)(5) of the term of U.S. Patent No. 6,406,699 is granted for a period of one year from the extended expiration date of the ‘699 patent.

Robert Bahr,
Deputy Commissioner for Patents, United States Patent and Trademark Office.