

with which a company deals—companies using highly sensitive information may be held to a higher standard of verification. Because verification may be costly for business, work needs to be done to arrive at appropriate, cost-effective ways to provide companies with the means to provide verification.

3. *Consequences.* For self-regulation to be effective, failure to comply with fair information practices should have consequences. Examples of such consequences include cancellation of the right to use a certifying seal or logo, posting the name of the non-complier on a "bad-actor" list, or disqualification from membership in an industry trade association. Non-compliers could be required to pay the costs of determining their non-compliance. Ultimately, sanctions should be stiff enough to be meaningful and swift enough to assure consumers that their concerns are addressed in a timely fashion. When companies make assertions that they are abiding by certain privacy practices and then fail to do so, they may be liable for deceptive practices and subject to action by the Federal Trade Commission or appropriate bank or financial regulatory authority.

**Shirl Kinney,**

*Deputy Assistant Secretary and Administrator.*

[FR Doc. 98-15063 Filed 6-4-98; 8:45 am]

BILLING CODE 3510-60-P

## DEPARTMENT OF COMMERCE

### Patent and Trademark Office

#### Patent Term Extension

**ACTION:** Proposed collection; comment request.

**SUMMARY:** The Department of Commerce (DOC), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on the continuing information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)), and by the Patent and Trademark Office (Office) in the performance of its statutory functions of processing applications for patent term extension as required by the Hatch-Waxman Act, 35 U.S.C. 156.

**DATES:** Written comments must be submitted on or before August 4, 1998.

**ADDRESSES:** Direct all written comments to Linda Engelmeier, Departmental Forms Clearance Officer, Department of Commerce, Room 5327, 14th and

Constitution Avenue, NW, Washington, DC 20230.

**FOR FURTHER INFORMATION CONTACT:**

Requests for additional information should be directed to the attention of Karin L. Tyson, at the Special Program Law Office, Office of the Deputy Assistant Commissioner for Patent Policy and Projects, Washington DC 20231, by telephone at (703) 305-9285 or by facsimile transmission to (703) 308-6916.

**SUPPLEMENTARY INFORMATION:**

#### I. Abstract

The Patent and Trademark Office (Office), together with the Secretary of Health and Human Services and the Department of Agriculture administers the Hatch-Waxman Act, e.g. 35 U.S.C. 156. This Act permits the Office to restore the patent term lost due to certain types of regulatory review by the Food and Drug Administration or the Department of Agriculture. Only patents for drug products, medical devices, food additives, and color additives are eligible for extension. The maximum length that a patent may be extended (the maximum of patent term that may be restored) is five years.

The Hatch-Waxman Act requires that an application for patent term extension be filed with the Office within 60 days of a product (approved product) that was subject to regulatory review receiving permission for commercial marketing or use from the Food and Drug Administration or the Department of Agriculture. Under 35 U.S.C. 156(d)(1), an application for patent term extension must identify the approved product, the patent to be extended, and the claims of the patent that claim the approved product, a method of use of the approved product, or a method of manufacturing the approved product. It must also set forth sufficient information for the Commissioner of the Patent and Trademark Office to determine the eligibility of the patent for extension and to enable the Commissioner and the Secretary of Health and Human Services or the Department of Agriculture to determine the length of extension. In addition, the application for patent term extension must provide a brief description of the activities undertaken by the applicant during the regulatory review period with respect to the approved product and the significant dates of these activities. If the information supplied is not sufficient for the Commissioner to determine the eligibility of the patent for extension, the rights that will be derived from the extension, or the period of extension, the Commissioner

may regard the application as informal and the applicant may provide a response, addressing any deficiencies. In addition, the Commissioner may require additional information; for example, to identify the holder of the regulatory approval or to elect a single patent for extension. An applicant may file a written declaration of withdrawal of an application for patent term extension. If a patent is finally determined not to be eligible for patent term extension, an applicant for patent term extension may request reconsideration of this decision.

Under 35 U.S.C. 156(d)(5), an interim extension for a patent may be granted if the regulatory review of a product is in the approval phase (i.e., the regulatory review period referenced in 35 U.S.C. 156(d)(5)(A) has begun), but the approval phase is expected to extend beyond the original expiration date of the patent. An application for interim extension is required to be filed in the period beginning six months and ending fifteen days before the term of the patent is set to expire. An application for interim extension must identify the product subject to regulatory review, the Federal Statute which requires its review, the patent for which interim extension is sought, including each claim of the patent which claims the product under regulatory review or a method of using or manufacturing the product, and information to enable the Commissioner to determine eligibility for extension under 35 U.S.C. 156(a)(1), (a)(2) and (a)(3). In addition, an application for interim extension must provide a brief description of the activities undertaken by the applicant during the applicable regulatory review period to date and the significant dates applicable to such activities. If the information supplied is not sufficient for the Commissioner to determine the eligibility of the patent for interim extension or the rights that will be derived from the interim extension, the Commissioner may regard the application as informal and the applicant may provide a response, addressing any deficiencies. In addition, the Commissioner may require additional information.

Under 35 U.S.C. 156(e)(2), an interim extension may be granted if the term of a patent for which an application for patent term extension has been submitted under 35 U.S.C. 156(d)(1), and which is eligible for extension, would expire before a certificate of extension is issued.

**II. Method of Collection**

By mail, facsimile transmission, or hand carried to the Patent and Trademark Office.

**III. Data**

OMB Number: 0651-0020.

Type of Review: Renewal with change.

Affected Public: Individuals or households, businesses or other for-profit, not-for-profit institutions, farms,

state, local or tribal governments, and the Federal Government.

Estimated Number of Respondents: 57.

Estimated Time Per Response: It is estimated to take the public 20 to 25 hours to complete an application for patent term extension under 35 U.S.C. 156(d)(1), an application for interim patent term extension under 35 U.S.C. 156(d)(5), or to petition for review of a final eligibility decision. In addition, it

is estimated to take the public 1 to 2 hours to file a request for an interim extension under 35 U.S.C. 156(e)(2), to respond to a requirement for additional information, and to file a written declaration of withdrawal. There are no forms associated with this information collection.

Estimated Total Annual Respondent Burden Hours: 1,302 hours per year.

Estimated Total Annual Respondent Cost Burden: \$227,850 per year.

Title of form	Form Nos.	Estimated time for response (hours)	Estimated annual burden hours	Estimated annual responses
Application to Extend Patent Term under 35 U.S.C. 156(d)(1).	No Forms Associated .....	25	1,250	50
Request for Interim Extension under 35 U.S.C. 156(e)(2) .....	No Forms Associated .....	1	1	1
Petition to Review Final Eligibility Decision .....	No Forms Associated .....	25	25	1
Application for Interim Extension under 35 U.S.C. 156(d)(5) .....	No Forms Associated .....	20	20	1
Response to Requirement to Elect .....	No Forms Associated .....	1	2	2
Response to Request to Identify Holder of Regulatory Approval.	No Forms Associated .....	2	2	1
Declaration to Withdraw an Application To Extend Patent Term.	No Forms Associated .....	2	2	1
Totals .....	.....	.....	1,302	57

**IV. Request for Comments**

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized or included in the request for OMB approval of this information collection; they will also become a matter of public record.

Dated: June 1, 1998.

**Linda Engelmeier,**

Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 98-14946 Filed 6-4-98; 8:45 am]

BILLING CODE 3510-16-P

**COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS****Adjustment of Import Limits for Certain Cotton and Man-Made Fiber Textile Products Produced or Manufactured in Pakistan**

June 1, 1998.

**AGENCY:** Committee for the Implementation of Textile Agreements (CITA).

**ACTION:** Issuing a directive to the Commissioner of Customs increasing limits.

**EFFECTIVE DATE:** June 8, 1998.

**FOR FURTHER INFORMATION CONTACT:** Ross Arnold, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482-4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 927-5850. For information on embargoes and quota re-openings, call (202) 482-3715.

**SUPPLEMENTARY INFORMATION:**

**Authority:** Section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854); Executive Order 11651 of March 3, 1972, as amended.

The current limits for certain categories are being increased for carryover.

A description of the textile and apparel categories in terms of HTS

numbers is available in the **CORRELATION:** Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 62 FR 66057, published on December 17, 1997). Also see 62 FR 63524, published on December 1, 1997.

**Troy H. Cribb,**

Chairman, Committee for the Implementation of Textile Agreements.

**Committee for the Implementation of Textile Agreements**

June 1, 1998.

Commissioner of Customs,  
Department of the Treasury, Washington, DC 20229.

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on November 25, 1997, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton and man-made fiber textile products, produced or manufactured in Pakistan and exported during the twelve-month period which began on January 1, 1998 and extends through December 31, 1998.

Effective on June 8, 1998, you are directed to increase the limits for the following categories, as provided for under the Uruguay Round Agreement on Textiles and Clothing:

Category	Adjusted limit <sup>1</sup>
237 .....	442,316 dozen.
239pt. <sup>2</sup> .....	1,910,245 kilograms.
335/635 .....	373,963 dozen.
336/636 .....	486,778 dozen.
341/641 .....	796,170 dozen
342/642 .....	394,062 dozen.