

Effect of Director's Decision

Section 503 of SMCRA provides that a State may not exercise jurisdiction under SMCRA unless the State program is approved by the Secretary. Similarly, 30 CFR 732.17(a) requires that any alteration of an approved State program be submitted to OSM for review as a program amendment. Thus, any changes to a State program are not enforceable until approved by OSM. The Federal regulations at 30 CFR 732.17(g) prohibit any unilateral changes to approved programs. In the oversight of the Ohio program, the Director will recognize only the approved program, together with any consistent implementing policies, directives, and other materials, and will require the enforcement by Ohio of such provisions.

VI. Procedural Determinations*Executive Order 12866*

This final rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).

Executive Order 12778

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778 (Civil Justice Reform) and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.15 and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination on whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR Parts 730, 731, and 732 have been met.

National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal which is the subject of this rule is based upon corresponding Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the corresponding Federal regulations.

List of Subjects in 30 CFR Part 935

Intergovernmental relations, Surface mining, Underground mining.

Dated: May 5, 1995.

Ronald C. Recker,

Acting Regional Director, Appalachian Regional Coordinating Center.

For the reasons set out in the preamble, Title 30, Chapter VII, Subchapter T of the Code of Federal Regulations is amended as set forth below:

PART 935—OHIO

1. The authority citation for Part 935 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

2. Section 935.15 is amended by adding new paragraph (www) to read as follows:

§ 935.15 Approval of regulatory program amendments.

* * * * *

(www) The following amendment (Program Amendment 68R) pertaining to the Ohio regulatory program, as submitted to OSM on May 17, 1994, and revised on March 1, 1995, is approved, effective May 12, 1995: Contemporaneous Reclamation.

[FR Doc. 95-11782 Filed 5-11-95; 8:45 am]
BILLING CODE 4310-05-M

DEPARTMENT OF COMMERCE**Patent and Trademark Office****37 CFR Part 1**

[Docket No. 950411099-5099-01]

RIN 0651-AA52

Amendment to Rules for Extension of Patent Term

AGENCY: Patent and Trademark Office, Commerce.

ACTION: Final rule.

SUMMARY: The Patent and Trademark Office (Office) is revising the rules directed to the extension of patent term to implement the provisions of Pub. L. 103-179, section 5; 107 Stat. 2040 codified at 35 U.S.C. 156(d)(5) and to clarify the requirements for eligibility. The amended rules establish procedures for the Commissioner to issue an interim extension of the term of a patent where the original term would expire before a product covered by the patent has received regulatory approval for commercial marketing or use. The amended rules also clarify that an application for patent term extension must be based on regulatory activities performed by the patent owner or its agent.

EFFECTIVE DATE: July 11, 1995.

FOR FURTHER INFORMATION CONTACT: Gerald A. Dost by telephone at (703) 305-9285 or by mail addressed to Commissioner of Patents and Trademarks, Washington, DC 20231 marked to the attention of Mr. Dost, Office of the Deputy Assistant Commissioner for Patent Policy and Projects, or by FAX to (703) 308-6916.

SUPPLEMENTARY INFORMATION: Patent term extension has been available under 35 U.S.C. 156 for patents that claim certain products that are subject to regulatory review before being commercially marketed or used. Prior to enactment of 35 U.S.C. 156(d)(5), eligibility for patent term extension was dependent on regulatory approval of the product before the original patent term expired. 35 U.S.C. 156(d)(5) has made it possible, under appropriate circumstances, to obtain interim extensions of patent term where the regulatory process is likely to extend beyond the expiration of the patent term.

One purpose of the amended rules is to revise the present regulations contained in 37 CFR part 1, subpart F, to include provisions for interim extension of the patent term prior to regulatory approval of the product that can now form the basis of patent term

extension. The amended rules set forth procedures that govern the content and submission of applications for an interim extension of a patent term, and procedures governing the interim extension determination and issuance of interim patent term extension certificates by the Office.

The initial guidelines directed to the preparation and filing of applications for interim extensions of patent terms as authorized by 35 U.S.C. 156(d)(5), were published as "Guidelines For Interim Extension Under 35 U.S.C. 156(d)(5) of a Patent Term Prior To Regulatory Approval of a Product For Commercial Marketing or Use—Public Law 103-179 (December 3, 1993)" in the Official Gazette at 1159 Off. Gaz. Pat. Office 12 (February 1, 1994). The Final Rule supplements these initial guidelines. To the extent that they conflict with the interim guidelines, the Final Rule governs.

It is important to keep in mind the distinction between an interim patent term extension under section 156(e)(2) and the interim patent term extension provided for by 35 U.S.C. 156(d)(5), under section 156(d)(5). The former applies *after* regulatory approval has occurred and is addressed in 37 CFR 1.760. Interim patent term extensions under section 156(e)(2) are not affected by the amendments to the rules. The latter applies *before* regulatory approval has occurred and is addressed in 37 CFR 1.780 and 1.790.

The eligibility criteria for obtaining an interim extension under section 156(d)(5) are substantially the same as for obtaining patent term extension under section 156 after regulatory approval has occurred. Under the provisions of 35 U.S.C. 156(d)(5), a patent owner or its agent may submit an application for an interim patent term extension within six months, but not later than 15 days, of the original expiration date of the patent. At the time the application is submitted, the regulatory review period must have advanced to the approval phase as defined in section 156(g), but must not have ended. For a new drug, for example, the approval phase is defined in section 156(g)(1)(B)(ii) as the period beginning on the date a new drug application was initially submitted for the new drug under § 505 of the Federal Food, Drug and Cosmetic Act.

The content of the application for interim extension is the same as for an application for patent term extension following regulatory review, with certain modifications necessitated by the circumstances. For example, the application for interim term extension will not be required to contain

information about regulatory approval since that event has not occurred. A fee is required for each interim extension application filed before regulatory approval occurs—\$400.00 for the initial application for interim extension and \$200.00 for each supplementary application for interim extension.

The processing of an application for interim patent term extension under 35 U.S.C. 156(d)(5), will not require transmission of a copy of the application to the regulatory agency. However, it is contemplated that the Office will consult with the regulatory agency, as it has been doing for the past 10 years under section 156, on the question of eligibility for patent term extension.

If the patent is eligible for extension but for the fact that it is still under regulatory review, the Office can extend the patent term in one-year increments not to exceed five years from the expiration date. Any such extension would terminate 60 days after market approval. Before the 60-day period expires, the patentee could submit an application for patent term extension, supplying any additional information necessary to obtain any additional extension available under section 156.

The interim extension of patent term available under section 156(d)(5) cannot exceed the extension from the original patent that would be available after regulatory approval. Thus, for example, a patent that was subject to the two-year extension limitation of section 156(g)(6)(C), could not obtain interim extension beyond two years from the original patent term expiration date. However, after an interim extension under section 156(d)(5) has been granted, the amount of patent term extension available after regulatory review is controlled by either section 156(d)(5) or section 156(g)(6) (A) or (B). In no case would the extension go beyond five years from the original expiration date of the patent. However, for those situations falling under section 156(g)(6)(C), where regulatory approval occurs within the two-year period after the original expiration date of the patent, the extension after approval is measured from the date on which the product receives permission for commercial marketing or use. Section 156(d)(5)(E)(ii).

Review of recent applications for patent term extension has revealed that the provisions of 37 CFR 1.785(c) may be read as being inconsistent with 35 U.S.C. 156. The statute further requires that an application for patent term extension be filed by the patent owner or its agent. 35 U.S.C. 156(d)(1). The statute further requires under section

156(d)(1)(D) a description of the activities undertaken by the applicant (i.e., the patent owner or its agent) during the regulatory review period, and specifies in section 156(d)(2)(B)(i) that the lack of due diligence by the applicant during the regulatory review period may be taken into account. Given these statutory requirements, the Office has held that in order to be eligible for patent term extension, the patent owner or its agent must have undertaken the activities that lead to regulatory approval. If a patent owner has not been involved, either directly or indirectly, in the regulatory review process, that patent owner has not lost any effective patent life since it never invested time and resources necessary to obtain approval for commercial marketing or use. Accordingly, to the extent that 37 CFR 1.785 could be interpreted to permit a patent owner to obtain a patent term extension where neither the patent owner nor its agent were responsible for activities leading to regulatory approval, it was misleading and contrary to both the letter and intent of section 156.

A notice of proposed rulemaking relating to Amendment to Rules for Extension of Patent Term was published in the **Federal Register**, 59 FR 56015, (November 10, 1994) and in the Official Gazette, 1169 Off. Gaz. Pat. Office 33 (December 13, 1994). A sole comment was received in response to this notice, but no change has been made in the text of the proposed amendments and additions to the rules.

The comment was directed to the proposed amendment to 37 CFR 1.785(c) when taken in light of 35 U.S.C. 156. The comment suggested that the party in interest before the regulatory agency (e.g., the Food and Drug Administration) should be the party to obtain a patent term extension, whether that party is the patent owner or licensee, and regardless of any "agency" relationship which may exist between the two with respect to such regulatory proceedings. This may be accomplished, it was argued, by construing the term "applicant" in 35 U.S.C. 156(d)(1)(D) and (d)(2)(B)(i) to mean the "applicant for regulatory approval."

In response, it is clear that under 35 U.S.C. 156(a)(3) and (d)(1), the "applicant" for the patent term extension shall be either the "owner of record of the patent" or the party which may be construed to be "its agent," which requirement is repeated in 35 U.S.C. 156(d)(5)(A) and (d)(5)(C) with regard to interim extensions. Indeed, to hold otherwise in the manner suggested in the comment would violate the plain meaning of 35 U.S.C. 156(c)(1), which requires that the patent term extension

period be reduced by the time that the "applicant for patent extension did not act with due diligence during such period of the regulatory review period." This section not only cites 35 U.S.C. 156(d)(2)(B) but also is consistent with the required description of activities undertaken during the applicable regulatory period set forth in 35 U.S.C. 156(d)(1)(D). The statute thus specifically requires that the application for patent term extension contain a description of the activities performed by the patent owner or its agent before the regulatory agency with regard to such proceedings, 35 U.S.C. 156(d)(1)(D), and further specifies that the lack of due diligence by the patent owner or its agent during the regulatory review period may be taken into account. 35 U.S.C. 156(c)(1) and (d)(2)(B)(i).

In addition to the constraints of the statutory language, the comment fails to identify any justification for granting a term extension on a patent where the patent owner has not, either directly or indirectly, incurred either the significant costs associated with regulatory approval or any delay in the commercial marketing of a product. Since the patent term extension provisions of section 156 are intended to be remedial in nature, providing a patent term extension to a patent owner who has not been harmed by the delay and costs associated with regulatory approval of a product would provide an unintended benefit to such a patent owner. In addition, providing a patent term extension to a patent owner that did not participate in the regulatory review process could also frustrate an important purpose of the statute, that is, to encourage companies to make the significant investment necessary to obtain regulatory approval and distribute the pharmaceutical product to the public rather than placing a non-participating patent owner in a position to keep the product off the market during the extended term, to the detriment of the party that made the significant investment necessary to obtain regulatory approval.

Accordingly, not only does the plain language of the statute prohibit the statutory interpretation suggested in the comment, but also the purpose of the statute would not be fulfilled by construing "applicant" to mean the applicant for regulatory review.

Discussion of Specific Rules

Section 1.750 is being amended, as proposed, to provide for an eligibility determination which will be made on applications for interim extension filed in compliance with § 1.790. The section

is further modified to limit the mailing of a notice of a final determination to applications filed in compliance with § 1.740 after the regulatory approval process is complete.

Section 1.750 is being amended, as proposed, to require that the title recite that the section is directed to requests for interim extensions of patent term under 35 U.S.C. 156(e)(2), to distinguish in from interim extensions available under 35 U.S.C. 156(d)(5), addressed in § 1.780.

Section 1.765(a) is being amended, as proposed, to change the phrase (two occurrences) "the Office of the Secretary" to read "the Office or the Secretary." The change provides that the applicant has a duty of disclosure to both the Patent and Trademark Office and the Secretary of Health and Human Services or the Secretary of Agriculture.

Section 1.780 is being amended, as proposed, to provide that a certificate of interim extension under 35 U.S.C. 156(d)(5) will be issued to the applicant. Section 1.780 also provides for notification of the issuance of the certificate of interim extension under 35 U.S.C. 156(d)(5), including the identity of the product currently under regulatory review, to be published in the **Federal Register**.

Section 1.785 is being amended, as proposed, to require the applicant for extension, i.e., the patent owner or its agent, to also have been the marketing applicant who obtained regulatory approval of the product for commercial marketing or use. While regulatory approval can be obtained by a party other than the patent owner, that other party must have been an agent of the patent owner when obtaining the regulatory approval in order for the patent owner to be eligible to apply for extension of the patent term.

Section 1.790 is being added, as proposed, to provide for one or more interim extensions for periods of up to one year for patents where the applicable regulatory review period described in paragraph (1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii) of 35 U.S.C. 156(g) that began for the patented product may extend beyond the expiration of the patent term in effect.

Paragraph (a) of added § 1.790 defines the time periods in which the initial interim extension application and each subsequent interim extension application must be filed in the Office. In no event will interim extensions be granted under proposed § 1.790 for a period of extension longer than that to which the applicant would be entitled to under 35 U.S.C. 156(c).

Paragraph (b) of added § 1.790 establishes that the content requirements for the initial interim extension applications are substantially the same as the content requirements for a formal application for extension of patent term under § 1.740 and a complete application under § 1.741, except that the content requirements relate to a product currently undergoing regulatory review. In other words, the interim extension applications contain information available to the patent owner or its agent at the time the application is filed.

Paragraph (c) of added § 1.790 permits each interim extension application after the initial interim extension application to be limited to a request for a subsequent interim extension along with a statement that the regulatory review period has not been completed and any materials or information required under §§ 1.740 and 1.741 not present in the preceding interim extension application.

Section 1.795 is being added, as proposed, to provide that any interim extension granted under 35 U.S.C. 156(d)(5) terminates at the end of the 60-day period beginning on the date on which the product involved receives permission for commercial marketing or use. If within that 60-day period the patent owner or its agent files additional information required under 35 U.S.C. 156(d)(1) not contained in the applications for interim extension, the patent shall be further extended in accordance with the provisions of 35 U.S.C. 156.

Other Considerations

These rule changes are in conformity with the requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, Executive Order 12612, and the Paperwork Reduction Act of 1980, 44 U.S.C. 35091 *et seq.*

The Assistant General Counsel for Legislation and Regulation of the Department of Commerce has certified to the Chief Counsel for Advocacy, Small Business Administration, that these rules will not have a significant economic impact on a substantial number of small entities (Regulatory Flexibility Act, 5 U.S.C. 605(b)), because the rules would affect only a very small number of patents eligible for interim patent term extension.

The Patent and Trademark Office has also determined that this notice has no Federalism implications affecting the relationship between the National Government and the States as outlined in Executive Order 12612.

These rule changes contain collection of information requirements subject to

the Paperwork Reduction Act of 1980, 44 U.S.C. 35 U.S.C. 156(d)(5) 3501 *et seq.*, which have previously been approved by the Office of Management and Budget under Control Number 0651-0020. The public reporting burden for this collection of information for Petition Extension is estimated to average 60 hours each, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collections of information. Send comments regarding this burden estimate, or any other aspect of this collection of information, including suggestions for reducing the burden, to Gerald A. Dost, Office of the Deputy Assistant Commissioner for Patent Policy and Projects, Box DAC, Washington, DC 20231, and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503 (ATTN: Paperwork Reduction Act Projects 0651-0020).

List of Subjects in 37 CFR Part 1

Administrative practice and procedure, Authority delegations (government agencies), Conflict of interest, Courts, Inventions and patents, Lawyers.

For the reasons set forth, the preamble, part 1 of title 37 of the Code of Federal Regulations is amended to read as follows:

PART 1—RULES OF PRACTICE IN PATENT CASES

1. The authority citation for 37 CFR part 1, subparts A and F continues to read as follows:

Authority: 35 U.S.C. 6, unless otherwise noted.

2. Section 1.20 is amended by revising paragraph (j) to read as follows:

§ 1.20 Post-issuance fees.

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(j) For filing an application for extension of the term of a patent.

(1) Application for extension under § 1.740	\$1,030.00
(2) Initial application for interim extension under § 1.790	400.00
(3) Subsequent application for interim extension under § 1.790	200.00

3. Section 1.750 is revised to read as follows:

§ 1.750 Determination of eligibility for extension of patent term.

A determination as to whether a patent is eligible for extension may be made by the Commissioner solely on the basis of the representations contained in the application for extension filed in compliance with § 1.740 or § 1.790. This determination may be delegated to appropriate Patent and Trademark Office officials and may be made at any time before the certificate of extension is issued. The Commissioner or other appropriate officials may require from applicant further information or make such independent inquiries as desired before a final determination is made on whether a patent is eligible for extension. In an application for extension filed in compliance with § 1.740, a notice will be mailed to applicant containing the determination as to the eligibility of the patent for extension and the period of time of the extension, if any. This notice shall constitute the final determination as to the eligibility and any period of extension of the patent. A single request for reconsideration of a final determination may be made if filed by the applicant within such time as may be set in the notice of final determination or, if no time is set, within one month from the date of the final determination. The time periods set forth herein are subject to the provisions of § 1.136.

4. In § 1.760, the heading is revised to read as follows:

§ 1.760 Interim extension of patent term under 35 U.S.C. 156(e)(2).

5. Section 1.765(a) is revised to read as follows:

§ 1.765 Duty of disclosure in patent term extension proceedings.

(a) A duty of candor and good faith toward the Patent and Trademark Office and the Secretary of Health and Human Services or the Secretary of Agriculture rests on the patent owner or its agent, on each attorney or agent who represents the patent owner and on every other individual who is substantively involved on behalf of the patent owner in a patent term extension proceeding. All such individuals who are aware, or become aware, of material information adverse to a determination of entitlement to the extension sought, which has not been previously made of record in the patent term extension proceeding must bring such information to the attention of the Office or the Secretary, as appropriate, in accordance with paragraph (b) of this section, as soon as it is practical to do so after the individual becomes aware of the

information. Information is material where there is a substantial likelihood that the Office or the Secretary would consider it important in determinations to be made in the patent term extension proceeding.

6. Section 1.780 is revised to read as follows:

§ 1.780 Certificate of extension of patent term.

If a determination is made pursuant to § 1.750 that a patent is eligible for extension and that the term of the patent is to be extended, a certificate of extension, under seal, or certificate of interim extension under 35 U.S.C. 156(d)(5) will be issued to the applicant for the extension of the patent term. Such certificate will be recorded in the official file of the patent and will be considered as part of the original patent. Notification of the issuance of the certificate of extension will be published in the Official Gazette of the Patent and Trademark Office. Notification of the issuance of the certificate of interim extension under 35 U.S.C. 156(d)(5), including the identity of the product currently under regulatory review, will be published in the Official Gazette of the Patent and Trademark Office and in the **Federal Register**. No certificate of extension will be issued if the term of the patent cannot be extended, even though the patent is otherwise determined to be eligible for extension. In such situations the final determination made pursuant to § 1.750 will indicate that no certificate will issue.

7. Section 1.785 is revised to read as follows:

§ 1.785 Multiple applications for extension of term of the same patent or of different patents for the same regulatory review period for a product.

(a) Only one patent may be extended for a regulatory review period for any product (§ 1.720(h)). If more than one application for extension of the same patent is filed, the certificate of extension of patent term, if appropriate, will be issued based upon the first filed application for extension.

(b) If more than one application for extension is filed by a single applicant which seeks the extension of the term of two or more patents based upon the same regulatory review period, and the patents are otherwise eligible for extension pursuant to the requirements of this subpart, in the absence of an election by the applicant, the certificate of extension of patent term, if appropriate, will be issued upon the application for extension of the patent term having the earliest date of issuance

of those patents for which extension is sought.

(c) If an application for extension is filed which seeks the extension of the term of a patent based upon the same regulatory review period as that relied upon in one or more applications for extension pursuant to the requirements of this subpart, the certificate of extension of patent term will be issued on the application only if the patent owner or its agent is the holder of the regulatory approval granted with respect to the regulatory review period.

(d) An application for extension shall be considered complete and formal regardless of whether it contains the identification of the holder of the regulatory approval granted with respect to the regulatory review period. When an application contains such information, or is amended to contain such information, it will be considered in determining whether an application is eligible for an extension under this section. A request may be made of any applicant to supply such information within a non-extendable period of not less than one (1) month whenever multiple applications for extension of more than one patent are received and rely upon the same regulatory review period. Failure to provide such information within the period for response set shall be regarded as conclusively establishing that the applicant is not the holder of the regulatory approval.

(e) Determinations made under this section shall be included in the notice of final determination of eligibility for extension of the patent term pursuant to § 1.750 and shall be regarded as part of that determination.

8. Section 1.790 is added to read as follows:

§ 1.790 Interim extension of patent term under 35 U.S.C. 156(d)(5).

(a) An owner of record of a patent or its agent who reasonably expects that the applicable regulatory review period described in paragraph (1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii) of subsection (g) that began for a product that is the subject of such patent may extend beyond the expiration of the patent term in effect may submit one or more applications for interim extensions for periods of up to one year each. The initial application for interim extension must be filed during the period beginning 6 months and ending 15 days before the patent term is due to expire. Each subsequent

application for interim extension must be filed during the period beginning 60 days before and ending 30 days before the expiration of the preceding interim extension. In no event will the interim extensions granted under this section be longer than the maximum period of extension to which the applicant would be entitled under 35 U.S.C. 156(c).

(b) A complete application for interim extension under this section shall include all of the information required for a formal application under § 1.740 and a complete application under § 1.741. Sections (a)(1), (a)(2), (a)(4), and (a)(6)–(a)(17) of § 1.740 and § 1.741 shall be read in the context of a product currently undergoing regulatory review. Sections (a)(3) and (a)(5) of § 1.740 are not applicable to an application for interim extension under this section.

(c) The content of each subsequent interim extension application may be limited to a request for a subsequent interim extension along with a statement that the regulatory review period has not been completed along with any materials or information required under § 1.740 and § 1.741 that are not present in the preceding interim extension application.

9. Section 1.791 is added to read as follows:

§ 1.791 Termination of interim extension granted prior to regulatory approval of a product for commercial marketing or use.

Any interim extension granted under 35 U.S.C. 156(d)(5) terminates at the end of the 60-day period beginning on the date on which the product involved receives permission for commercial marketing or use. If within that 60-day period the patent owner or its agent files an application for extension under § 1.740 and § 1.741 including any additional information required under 35 U.S.C. 156(d)(1) not contained in the application for interim extension, the patent shall be further extended in accordance with the provisions of 35 U.S.C. 156.

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Dated: May 8, 1995.

Bruce A. Lehman,

*Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks.*

[FR Doc. 95–11787 Filed 5–11–95; 8:45 am]

BILLING CODE 3510–16–M

**ENVIRONMENTAL PROTECTION
AGENCY**

40 CFR Parts 261 and 302

[SWH–FRL–5206–4]

RIN 2050–AD59

**Hazardous Waste Management
System; Carbamate Production
Identification and Listing of Hazardous
Waste; and CERCLA Hazardous
Substance Designation and Reportable
Quantities; Correction**

AGENCY: Environmental Protection Agency.

ACTION: Final rule; correction.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is correcting minor errors in the amendments to the regulations which appeared in the **Federal Register** on April 17, 1995 (60 FR 19165).

EFFECTIVE DATE: August 9, 1995.

FOR FURTHER INFORMATION CONTACT: For information concerning this notice, please contact John Austin, Office of Solid Waste (5304), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460, (202) 260–4789.

SUPPLEMENTARY INFORMATION: In the February 9, 1995 final rule (60 FR 7824), EPA designated a number of discarded commercial chemical products, off-specification species, container residues, and spill residues as hazardous wastes. EPA subsequently corrected typographical and omission errors in the listing of these chemicals in the notice of April 17, 1995 (60 FR 19165). Today EPA is correcting a typo and an omission to the April document.

The correction notice incorrectly states the Chemical Abstract Number (CAS) for the substance Mexacarbate. The correct CAS number is 315–18–4. The correction notice also fails to include the addition of the substance sodium diethyldithiocarbamate to the Appendix A list of the additions to CERCLA Section 302.4 in numerical sequence of their CAS Registry numbers. The Agency is amending Appendix A to § 302.4 to reflect the additions to § 304.4 that were finalized by the February 9, 1995 document.

Dated: May 8, 1995.

Elliott P. Laws,

Assistant Administrator, Office of Solid Waste and Emergency Response.

Accordingly, the publication on April 17, 1995 of corrections to the final regulations, which were the subject of FR Doc. 95–2983, is corrected as follows: