(3) *Limitations.* Do not use in horses intended for human consumption.

Dated: December 29, 2004.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 05–523 Filed 1–10–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Lincomycin Hydrochloride Soluble Powder

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Cross Vetpharm Group Ltd. The ANADA provides for oral use of lincomycin soluble powder to make medicated drinking water for administration to swine for the treatment of swine dysentery or to broiler chickens for the control of necrotic enteritis.

DATES: This rule is effective January 11, 2005.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV 104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: *lonnie.luther@fda.gov*.

SUPPLEMENTARY INFORMATION: Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland, filed ANADA 200–377 for LINCOMED (lincomycin hydrochloride) Soluble Powder. The application provides for oral use of lincomycin soluble powder to make medicated drinking water for administration to swine for the treatment of swine dysentery or to broiler chickens for the control of necrotic enteritis. Cross Vetpharm Group Ltd.'s LINCOMED Soluble Powder is approved as a generic copy of Pharmacia & Upjohn Co.'s LINCOMIX Soluble Powder, approved under NADA 111–636. ANADA 200–377 is approved as of December 6, 2004, and the regulations are amended in 21 CFR 520.1263c to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

FDA has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 520

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. Section 520.1263c is amended by revising paragraph (b) to read as follows:

§ 520.1263c Lincomycin hydrochloride soluble powder.

* * * * *

(b) *Sponsors.* See Nos. 000009, 046573, 054925, 059130, and 061623 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

* * * * *

Dated: December 29, 2004 .

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 05–524 Filed 1–10–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Parts 1 and 3

[Docket No.: 2004–P–034]

RIN 0651–AB76

Changes To Implement the Cooperative Research and Technology Enhancement Act of 2004

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Interim rule.

SUMMARY: The Cooperative Research and Technology Enhancement Act of 2004 (CREATE Act) amends the patent laws to provide that subject matter developed by another person shall be treated as owned by the same person or subject to an obligation of assignment to the same person for purposes of determining obviousness if three conditions are met: The claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made; the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement. The United States Patent and Trademark Office (Office) is revising the rules of practice in patent cases to implement the CREATE Act.

DATES: Effective Date: December 10, 2004.

Comment Deadline Date: To be ensured of consideration, written comments must be received on or before February 10, 2005. No public hearing will be held.

ADDRESSES: Comments should be sent by electronic mail message over the Internet addressed to: *ab76comments@uspto.gov*. Comments may also be submitted by mail addressed to: Box Comments—Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA, 22313–1450, or by facsimile to (571) 273–7735, marked to the attention of Robert A. Clarke. Although comments may be submitted by mail or facsimile, the Office prefers to receive comments via the Internet. If comments are submitted by mail, the Office prefers that the comments be submitted on a DOS formatted 3½ inch disk accompanied by a paper copy.

Comments may also be sent by electronic mail message over the Internet via the Federal eRulemaking Portal. See the Federal eRulemaking

Portal Web site (*http://www.regulations.gov*) for additional instructions on providing comments via the Federal eRulemaking Portal.

The comments will be available for public inspection at the Office of the Commissioner for Patents, located in Madison East, Tenth Floor, 600 Dulany Street, Alexandria, Virginia, and will be available through anonymous file transfer protocol (ftp) via the Internet (address: *http://www.uspto.gov*). Because comments will be made available for public inspection, information that is not desired to be made public, such as an address or phone number, should not be included in the comments.

FOR FURTHER INFORMATION CONTACT: Robert A. Clarke, or Jeanne M. Clark, Senior Legal Advisors, Office of Patent Legal Administration, Office of the Deputy Commissioner for Patent Examination Policy, by telephone at (571) 272–7704, by mail addressed to: Box Comments—Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313–1450, or by facsimile to (571) 273–7735, marked to the attention of Robert A. Clarke.

SUPPLEMENTARY INFORMATION: The CREATE Act amends 35 U.S.C. 103(c) to provide that subject matter developed by another person shall be treated as owned by the same person or subject to an obligation of assignment to the same person for purposes of determining obviousness if three conditions are met: (1) The claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made; (2) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and (3) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement. *See* Pub. L. 108–453, 118 Stat. 3596 (2004). Section 2 of the CREATE Act specifically amends 35 U.S.C. 103(c) to provide that:

(c)(1) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.

(2) For purposes of this subsection, subject matter developed by another person and a claimed invention shall be deemed to have been owned by the same person or subject to an obligation of assignment to the same person if—

(A) The claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made;

(B) The claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and

(C) The application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.

(3) For purposes of paragraph (2), the term ''joint research agreement'' means a written contract, grant, or cooperative agreement entered into by two or more persons or entities for the performance of experimental, developmental, or research work in the field of the claimed invention.

Section 3 of the CREATE Act provides that its amendments shall apply to any patent (including any reissue patent) granted on or after December 10, 2004. The CREATE Act provides that its amendments shall not affect any final decision of a court or the Office rendered before December 10, 2004, and shall not affect the right of any party in any action pending before the Office or a court on December 10, 2004, to have that party's rights determined on the basis of the provisions of title 35, United States Code, in effect on December 9, 2004. Since the CREATE Act also includes the amendment to 35 U.S.C. 103(c) made by section 4807 of the American Inventors Protection Act of 1999 (*see* Pub. L. 106–113, 113 Stat. 1501, 1501A–591 (1999)), the change of ''subsection (f) or (g)'' to ''one or more of subsections (e), (f), or (g)'') in 35 U.S.C. 103(c) is now also applicable to applications filed prior to December 29, 1999, that were pending on December 10, 2004.

This interim rule revises the rules of practice in title 37 of the Code of Federal Regulations (CFR) to implement the CREATE Act.

Once an examiner has established a *prima facie* case of obviousness under 35 U.S.C. 103(a), the burden of overcoming the rejection by invoking 35 U.S.C. 103(c) as amended by the CREATE Act is on the applicant. To overcome a rejection under 35 U.S.C. 103(a) based upon subject matter (whether a patent document, publication, or other evidence) which qualifies as prior art under only one or more of 35 U.S.C. 102(e), (f) or (g) via the CREATE Act, the applicant must provide a statement to the effect that the prior art and the claimed invention were made by or on the behalf of parties to a joint research agreement within the meaning of 35 U.S.C. 103(c)(3), and that the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement. 35 U.S.C. 103(c)(3) defines a ''joint research agreement'' as a written contract, grant, or cooperative agreement entered into by two or more persons or entities for the performance of experimental, developmental, or research work in the field of the claimed invention, that was in effect on or before the date the claimed invention (under examination or reexamination) was made. The statement must be or begin on a separate sheet and must not also be directed to other matters (§ 1.4(c)). The statement must be signed either by the applicant or by the assignee of the entire interest (as provided for under § 3.71(b)).

In addition to providing a statement, the applicant must also: (1) Amend the specification to disclose the names of the parties to the joint research agreement; and (2) either amend the specification to either set forth the date the joint research agreement was executed and a concise statement of the field of the claimed invention, or specify where (*i.e.*, by reel and frame number) this information is recorded in the assignment records of the Office. If the applicant disqualifies the subject matter relied upon by the examiner in accordance with 35 U.S.C. 103(c) as amended by the CREATE Act and the procedures set forth in this interim rule, the examiner will treat the application under examination and the 35 U.S.C. 102(e), (f), or (g) prior art as if they are commonly owned for purposes of 35 U.S.C. 103.

35 U.S.C. 103(c), as amended by the CREATE Act, continues to apply only to subject matter which qualifies as prior art under 35 U.S.C. 102(e), (f) or (g), and which is being relied upon in a rejection under 35 U.S.C. 103. If the rejection is anticipation under 35 U.S.C. 102(e), (f), or (g), 35 U.S.C. 103(c) cannot be relied upon to disqualify the subject matter in order to overcome the anticipation rejection.

Because the CREATE Act applies only to patents granted on or after December 10, 2004, the recapture doctrine may prevent the presentation of claims in reissue applications that had been amended or cancelled (*e.g.*, to avoid a rejection under 35 U.S.C. 103(a) based upon subject matter that may now be disqualified under the CREATE Act) during the prosecution of the application which resulted in the patent being reissued. *See* H.R. Rep. No. 108–425, at 6–7 (2003).

Discussion of Specific Rules

Section 1.71: Section 1.71 is amended to add new § 1.71(g). Section 1.71(g) provides that the specification may disclose or be amended to disclose the names of the parties to a joint research agreement. The application must disclose or be amended to disclose the names of the parties to a joint research agreement to invoke the ''safe harbor'' provision of 35 U.S.C. 103(c) as amended by the CREATE Act. *See* 35 U.S.C. 103(c)(2)(C). Section 1.71(g)(1) specifically provides that if the specification discloses (or is amended to disclose) the names of the parties to a joint research agreement for purposes of 35 U.S.C. 103(c)(2), the specification must also provide certain information necessary to determine the applicability of the ''safe harbor'' provision of 35 U.S.C. 103(c) (or specify where such information is recorded by reel and frame number in the assignment records of the Office). The specification must also include the name of each party to the joint research agreement because this information is required by 35 U.S.C. 103(c)(2)(C). The date the joint research agreement was executed must also be provided because this information is necessary to determine whether the ''joint research agreement * * * was in effect on or before the date the claimed invention was made'' as required by 35 U.S.C. 103(c)(2)(A). If a joint research agreement was amended to be in compliance with 35 U.S.C. 103(c) as amended by the CREATE Act, the date the amended joint research agreement was executed is the date the joint research agreement was executed for purposes of 35 U.S.C. 103(c)(2)(A) and is the date that must be provided to comply with § 1.71(g). A concise statement of the field of the claimed invention must also be provided because this information is necessary to determine whether ''the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement'' as required by 35 U.S.C. 103(c)(2)(B).

Section 1.71(g)(2) provides that an amendment under § 1.71(g)(1) must be accompanied by the processing fee set forth in § 1.17(i) if it is not filed within one of the following time periods: (1) Within three months of the filing date of a national application; (2) within three months of the date of entry of the national stage as set forth in § 1.491 in an international application; (3) before the mailing of a first Office action on the merits; or (4) before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.

Section 1.71(g)(3) provides that an amendment under § 1.71(g)(1) filed after the date the issue fee is paid must also be accompanied by the processing fee set forth § 1.17(i), and that the patent may not include the names of the parties to the joint research agreement. Section 1.71(g)(3) also provides that if the patent does not include the names of the parties to the joint research agreement, the amendment to include the names of the parties to the joint research agreement will not be effective unless the patent is corrected by a certificate of correction under 35 U.S.C. 255 and § 1.322. The requirements of § 1.71(g)(3) (payment of the processing fee set forth in § 1.17(i) and correction of the patent by a certificate of correction under 35 U.S.C. 255 and § 1.322) also apply in the situation in which such an amendment is not filed until after the date the patent was granted (in a patent granted on or after December 10, 2004). It is unnecessary to file a reissue application or request for reexamination of the patent to submit the amendment and other information necessary to take advantage of 35 U.S.C. 103(c) as amended by the CREATE Act. *See* H.R. Rep. No. 108–425, at 9 (''[t]he omission of the names of parties to the agreement is not an error that would justify commencement of a reissue or reexamination proceeding'').

The submission of such an amendment remains subject to the rules of practice: *e.g.*, §§ 1.116, 1.121, and 1.312. For example, if an amendment under § 1.71(g) is submitted in an application under final rejection to overcome a rejection under 35 U.S.C. 103(a) based upon a U.S. patent which qualifies as prior art only under 35 U.S.C. 102(e), the examiner may refuse to enter the amendment under § 1.71(g) if it is not accompanied by an appropriate terminal disclaimer (§ 1.321(d)). Such an amendment may necessitate the reopening of prosecution and entry of a double patenting rejection (§ 1.116).

If an amendment under § 1.71(g) is submitted to overcome a rejection under 35 U.S.C. 103(a) based upon a U.S. patent or U.S. patent application publication which qualifies as prior art only under 35 U.S.C. 102(e), and the examiner withdraws the rejection under 35 U.S.C. 103(a), but issues an Office action containing a new double patenting rejection based upon the disqualified patent or patent application publication, the Office action can be made final (provided that the examiner introduces no other new ground of rejection that was not necessitated by either amendment or an information disclosure statement filed during the time period set forth in § 1.97(c) with the fee set forth in § 1.17(p)). The Office action is properly made final because the new double patenting rejection was necessitated by amendment of the application by applicant. This is the case regardless of whether the claims themselves have been amended.

Section 1.77: Section 1.77 is amended to provide for the names of the parties to a joint research agreement in the preferred arrangement of the specification.

Section 1.104: Section 1.104(c)(4) is amended for consistency with the amendment to 35 U.S.C. 103(c).

Section 1.109: Section 1.109 is added to set forth the conditions under which the Office will make a double patenting rejection. Section 1.109(a) contains the provisions of § 1.130(b) (with a few changes for clarity). Section 1.130(b) is being removed from § 1.130 (see discussion of § 1.130).

Section 1.109(b) provides for double patenting situations which may arise as a result of the CREATE Act. Congress recognized that this amendment to 35 U.S.C. 103(c) would result in situations in which there would be double patenting between applications not owned by the same party. *See* H.R. Rep. No. 108–425, at 5–6 (2003). Therefore, § 1.109(b) provides that a double patenting rejection will be made in an application or patent under reexamination if: (1) The application or patent under reexamination claims an invention that is not patentably distinct from an invention claimed in a non-commonly owned patent; (2) the application or patent and the non-commonly owned patent are by or on behalf of parties to a joint research agreement; and (3) the inventions claimed in the application or patent and in the non-commonly owned patent were made as a result of activities undertaken within the scope of the joint research agreement. Thus, the application or patent and the subject matter disqualified under 35 U.S.C. 103(c) as amended by the CREATE Act will be treated as commonly owned for purposes of double patenting analysis. Section 1.109(b) also provides that this double patenting rejection will be made regardless of whether the application or patent and the non-commonly owned patent have the same or a different inventive entity. Section 1.109(b) also provides that this double patenting rejection may be obviated by filing a terminal disclaimer in accordance with § 1.321(d).

Section 1.130: Section 1.130 is amended to remove and reserve § 1.130(b).

Section 1.321: Section 1.321(d) is added to provide the terminal disclaimer requirements for the double patenting situations which arise as a result of the CREATE Act. *See* H.R. Rep. No. 108–425, at 6 (the Office may require a terminal disclaimer when double patenting is determined to exist for two or more claimed inventions for any application for which the applicant takes advantage of the ''safe harbor'' provision in 35 U.S.C. 103(c) as amended by the CREATE Act). The legislative history of the CREATE Act specifically states that:

> Congress intends that parties who seek to benefit from this Act to waive the right to enforce any patent separately from any earlier patent that would otherwise have formed the basis for an obviousness-type double patenting rejection. Further, Congress intends that parties with an interest in a patent that is granted solely on the basis of the amendments made pursuant to this Act to waive requirements for multiple licenses. In other words, the requirements under current law for parties to terminally disclaim interests in patents that would otherwise be invalid on ''obviousness-type'' double patenting grounds are to apply, *mutatis mutandis*, to the patents that may be issued in circumstances made possible by this Act.

See id.

Section 1.321(d) specifically sets forth the requirements for a terminal disclaimer that is filed in a patent application or in a reexamination proceeding to obviate a double patenting rejection based upon a U.S. patent or application that is not commonly owned but was disqualified under 35 U.S.C. 103(c). First, the terminal disclaimer must comply with the provisions of §§ 1.321(b)(2) through (b)(4). Second, the terminal disclaimer must be signed by the applicant in accordance with § 1.321(b)(1) if filed in a patent application, or be signed by the patentee in accordance with § 1.321(a)(1) if filed in a reexamination proceeding. Third, the terminal disclaimer must also be signed by the patentee or by the applicant, or an attorney or agent of record, of the disqualified patent or application. Fourth, the terminal disclaimer must also include a provision that the owner of the rejected application or patent and the owner of the disqualified patent or application each: (1) Waive the right to separately enforce and license the rejected application or patent and the disqualified patent or application; (2) agree that the rejected application or patent and the disqualified patent or application shall be enforceable during the period that the rejected patent or application and the disqualified patent or application are not separately enforced and are not separately licensed; and (3) agree that such waiver and agreement shall be binding upon the owner of the rejected application or patent, its successors, or assigns, and the owner of the disqualified patent or application, its successors, or assigns.

Section 3.11: Section 3.11(c) is added to provide that the Office will record a joint research agreement or an excerpt of a joint research agreement as provided in 37 CFR part 3. Section 3.11(c) also provides that such a joint research agreement or excerpt of a joint research agreement must include the name of each party to the joint research agreement, the date the joint research agreement was executed, and a concise statement of the field of invention (see § 1.71(g)).

Section 3.31: Section 3.31(g) is added to set forth the requirements for the cover sheet required by § 3.28 seeking to record a joint research agreement or an excerpt of a joint research agreement as provided by § 3.11(c). First, the cover sheet must identify the document as a ''joint research agreement'' (preferably, in the space provided for the description of the interest conveyed or transaction to be recorded in box 3 (under ''other'') of Office form PTO–1595 (June 2004)). Second, the cover sheet must indicate the name of the owner of the application or patent (preferably, in the space provided for the name and address of the party receiving the interest in box 2 of Office form PTO–1595). Third, the cover sheet must indicate the name of every other party to the joint research agreement party (preferably, in the space provided for the name of the party conveying the interest in box 1 (providing additional names on an attached sheet if necessary) of Office form PTO–1595). Fourth, the cover sheet must indicate the date the joint research agreement was executed (preferably, in the space provided for the execution date in box 1 of Office form PTO–1595).

Rule Making Considerations

Administrative Procedure Act: Pursuant to authority at 5 U.S.C. 553(b)(B), the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office finds good cause to adopt the changes made in this interim rule without prior notice and opportunity for public comment, as such prior notice and comment procedures are contrary to the public interest in this situation. The amendments to 35 U.S.C. 103(c) in the CREATE Act apply to any patent granted on or after December 10, 2004, and thus apply to applications currently pending before the Office. The rules of practice, however, do not currently provide for the amendment of an application or the recording of joint research agreements (or excerpts of joint research agreements) to invoke the ''safe harbor'' provision of 35 U.S.C. 103(c) as amended by the CREATE Act, and do not permit the filing of the type of terminal disclaimer necessary to overcome the double patenting rejection that may arise as a result of the CREATE Act. Delay in the promulgation of the changes in this rule to provide notice and comment procedures might cause harm to those applicants whose applications are currently under a 35 U.S.C. 103 rejection which could be overcome by invoking the ''safe harbor'' provision of 35 U.S.C. 103(c) as amended by the CREATE Act. Put simply, delay in the implementation of the CREATE Act might cause harm to those applicants who need to invoke its provisions promptly to avoid a loss of patent rights.

In addition, the changes in this interim rule relate solely to the procedures to be followed in prosecuting a patent application: *i.e.*, submitting the amendment necessary to invoke the ''safe harbor'' provision of 35 U.S.C. 103(c) as amended by the CREATE Act, filing of the type of terminal disclaimer necessary to overcome the double patenting rejection that may arise as a result of the CREATE Act, and submitting joint research agreements or excerpts of joint research agreements for recording by the Office. Therefore, these rule changes involve interpretive rules, or rules of agency practice and procedure under 5 U.S.C. 553(b)(A), and prior notice and an opportunity for public comment were not required pursuant to 5 U.S.C. 553(b)(A) (or any other law). *See Bachow Communications Inc.* v. *FCC,* 237 F.3d 683, 690 (D.C. Cir. 2001) (rules governing an application process are ''rules of agency organization, procedure, or practice'' and are exempt from the Administrative Procedure Act's notice and comment requirement); *see also Merck & Co., Inc.* v. *Kessler,* 80 F.3d 1543, 1549–50, 38 USPQ2d 1347, 1351 (Fed. Cir. 1996) (the rules of practice promulgated under the authority of former 35 U.S.C. 6(a) (now in 35 U.S.C. 2(b)(2)) are not substantive rules (to which the notice and comment requirements of the Administrative Procedure Act apply)), and *Fressola* v. *Manbeck*, 36 USPQ2d 1211, 1215 (D.D.C. 1995) (''it is doubtful whether any of the rules formulated to govern patent and trade-mark practice are other than 'interpretative rules, general statements of policy, * * * procedure,

or practice.' '') (quoting C.W. Ooms, *The United States Patent Office and the Administrative Procedure Act,* 38 Trademark Rep. 149, 153 (1948)). Accordingly, prior notice and an opportunity for public comment were not required pursuant to 5 U.S.C. 553(b)(A) (or any other law), and thirty-day advance publication is not required pursuant to 5 U.S.C. 553(d) (or any other law).

Regulatory Flexibility Act: As discussed previously, the changes in this interim rule involve rules of agency practice and procedure under 5 U.S.C. 553(b)(A), and prior notice and an opportunity for public comment were not required pursuant to 5 U.S.C. 553(b)(A) (or any other law). As prior notice and an opportunity for public comment were not required pursuant to 5 U.S.C. 553 (or any other law) for the changes in this interim rule, a regulatory flexibility analysis under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) is not required for the changes in this interim rule. *See* 5 U.S.C. 603.

Executive Order 13132: This rule making does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (Aug. 4, 1999).

Executive Order 12866: This rule making has been determined to be significant for purposes of Executive Order 12866 (Sept. 30, 1993).

Paperwork Reduction Act: This rule making involves information collection requirements which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The collections of information involved in this interim rule have been reviewed and previously approved by OMB under the following control numbers: 0651–0027, 0651–0031, 0651–0032, and 0651–0033. The United States Patent and Trademark Office is not resubmitting the information collections listed above to OMB for its review and approval because the changes in this notice do not affect the information collection requirements associated with these information collections.

The title, description and respondent description of each of the information collections is shown below with an estimate of the annual reporting burdens. Included in the estimate is the time for reviewing instructions, gathering and maintaining the data needed, and completing and reviewing the collection of information. The principal impacts of the changes in this rule making are to implement the CREATE Act.

OMB Number: 0651–0027.

Title: Recording Assignments.

Form Numbers: PTO–1594 and PTO–1595.

Type of Review: Approved through June of 2005.

Affected Public: Individuals or households, business or other for-profit institutions, not-for-profit institutions, farms, Federal Government, and State, Local, or Tribal Governments.

Estimated Number of Respondents: 240,345.

Estimated Time Per Response: 30 minutes.

Estimated Total Annual Burden Hours: 120,173 hours.

Needs and Uses: The Office records over 200,000 assignments or documents related to ownership of patent and trademark cases each year. The Office requires a cover sheet to expedite the processing of these documents and to ensure that they are properly recorded.

OMB Number: 0651–0031.

Title: Patent Processing (Updating).

Form Numbers: PTO/SB/08A, PTO/SB/08B, PTO/SB/17i, PTO/SB/17p, PTO/SB/21–27, PTO/SB/30–37, PTO/SB/42–43, PTO/SB/61–64, PTO/SB/64A, PTO/SB/67–68, PTO/SB/91–92, PTO/SB/96–97, PTO–2053–A/B, PTO–2054–A/B, PTO–2055–A/B, PTOL–413A.

Type of Review: Approved through July of 2006.

Affected Public: Individuals or households, business or other for-profit institutions, not-for-profit institutions, farms, Federal Government and State, Local and Tribal Governments.

Estimated Number of Respondents: 2,281,439.

Estimated Time Per Response: 1 minute and 48 seconds to 8 hours.

Estimated Total Annual Burden Hours: 2,731,841 hours.

Needs and Uses: During the processing for an application for a patent, the applicant/agent may be required or desire to submit additional information to the United States Patent and Trademark Office concerning the examination of a specific application. The specific information required or which may be submitted includes: Information disclosure statements and citations, requests for extensions of time, the establishment of small entity status; abandonment and revival of abandoned applications, disclaimers, requests for expedited examination of design applications, transmittal forms, requests to inspect, copy and access patent applications, nonpublication requests, certificates of mailing or transmission, submission of priority documents and amendments.

OMB Number: 0651–0032.

Title: Initial Patent Application.

Form Number: PTO/SB/01–07, PTO/SB/13PCT, PTO/SB/16–19, PTO/SB/29 and 29A, PTO/SB/101–110.

Type of Review: Approved through July of 2006.

Affected Public: Individuals or households, business or other for-profit institutions, not-for-profit institutions, farms, Federal Government, and State, Local, or Tribal Governments.

Estimated Number of Respondents: 454,287.

Estimated Time Per Response: 22 minutes to 10 hours and 45 minutes.

Estimated Total Annual Burden Hours: 4,171,568 hours.

Needs and Uses: The purpose of this information collection is to permit the Office to determine whether an application meets the criteria set forth in the patent statute and regulations. The standard Fee Transmittal form, New Utility Patent Application Transmittal form, New Design Patent Application Transmittal form, New Plant Patent Application Transmittal form, Declaration, Provisional Application Cover Sheet, and Plant Patent Application Declaration will assist applicants in complying with the requirements of the patent statute and regulations, and will further assist the USPTO in processing and examination of the application.

OMB Number: 0651–0033.

Title: Post Allowance and Refiling.

Form Numbers: PTO/SB/44, PTO/SB/50–51, PTO/SB/51S, PTO/SB/52–53, PTO/SB/56–58, PTOL–85B.

Type of Review: Approved through April of 2007.

Affected Public: Individuals or households, business or other for-profit institutions, not-for-profit institutions, farms, Federal Government, and State, Local or Tribal Governments.

Estimated Number of Respondents: 223, 411.

Estimated Time Per Response: 1.8 minutes to 2 hours.

Estimated Total Annual Burden Hours: 67,261 hours.

Needs and Uses: This collection of information is required to administer the patent laws pursuant to Title 35, U.S.C., concerning the issuance of patents and related actions including correcting errors in printed patents, refiling of patent applications, requesting reexamination of a patent, and requesting a reissue patent to correct an error in a patent. The affected public includes any individual or institution whose application for a patent has been allowed or who takes action as covered by the applicable rules.

Comments are invited on: (1) Whether the collection of information is necessary for proper performance of the functions of the agency; (2) the accuracy of the agency's estimate of the burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information to respondents.

Interested persons are requested to send comments regarding these information collections, including suggestions for reducing this burden, to Robert J. Spar, Director, Office of Patent Legal Administration, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313–1450, or to the Office of Information and Regulatory Affairs, OMB, 725 17th Street, NW., Washington, DC 20503, (Attn: PTO Desk Officer).

Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB control number.

List of Subjects

37 CFR Part 1

Administrative practice and procedure, Courts, Freedom of information, Inventions and patents, Reporting and recordkeeping requirements, Small businesses.

37 CFR Part 3

Administrative practice and procedure, Inventions and patents, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, 37 CFR parts 1 and 3 are amended as follows:

PART 1—RULES OF PRACTICE IN PATENT CASES

■ 1. The authority citation for 37 CFR part 1 continues to read as follows:

Authority: 35 U.S.C. 2(b)(2).

■ 2. Section 1.71 is amended by adding a new paragraph (g) to read as follows:

§ 1.71 Detailed description and specification of the invention.

* * * * *

(g) The specification may disclose or be amended to disclose the names of the parties to a joint research agreement (35 U.S.C. 103(c)(2)(C)).

(1) If the specification discloses or is amended to disclose the names of the parties to a joint research agreement for purposes of 35 U.S.C. 103(c)(2), the specification must also provide or be amended to provide the following information, or the location where (*i.e.*, by reel and frame number) such information is recorded in the assignment records of the Office:

(i) The date the joint research agreement was executed; and

(ii) A concise statement of the field of the claimed invention.

(2) An amendment under paragraph (g)(1) of this section must be accompanied by the processing fee set forth § 1.17(i) if not filed within one of the following time periods:

(i) Within three months of the filing date of a national application;

(ii) Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;

(iii) Before the mailing of a first Office action on the merits; or

(iv) Before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.

(3) An amendment under paragraph (g)(1) of this section filed after the date the issue fee is paid must be accompanied by the processing fee set forth § 1.17(i), and the patent may not include the names of the parties to the joint research agreement. If the patent does not include the names of the parties to the joint research agreement, the amendment to include the names of the parties to the joint research agreement will not be effective unless the patent is corrected by a certificate of correction under 35 U.S.C. 255 and § 1.322.

■ 3. Section 1.77 is amended by redesignating paragraphs (b)(4) through (b)(11) as paragraphs (b)(5) through (b)(12), adding a new paragraph (b)(4), and revising paragraph (c) to read as follows:

§ 1.77 Arrangement of application elements.

* * * * *

(b) * * *

(4) The names of the parties to a joint research agreement.

* * * * *

(c) The text of the specification sections defined in paragraphs (b)(1) through (b)(12) of this section, if applicable, should be preceded by a section heading in uppercase and without underlining or bold type.

■ 4. Section 1.104 is amended by revising paragraph (c)(4) to read as follows:

§ 1.104 Nature of examination.

* * * * *

(c) * * *

(4) Subject matter which is developed by another person which qualifies as prior art only under 35 U.S.C. 102(e), (f) or (g) may be used as prior art under 35 U.S.C. 103 against a claimed invention unless the entire rights to the subject matter and the claimed invention were commonly owned by the same person or organization or subject to an obligation of assignment to the same person or organization at the time the claimed invention was made.

(i) Subject matter developed by another person and a claimed invention shall be deemed to have been commonly owned by the same person or organization, or subject to an obligation of assignment to the same person or organization in any application and in any patent granted on or after December 10, 2004, if:

(A) The claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made;

(B) The claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and

(C) The application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.

(ii) For purposes of paragraph (c)(4)(i) of this section, the term ''joint research agreement'' means a written contract, grant, or cooperative agreement entered into by two or more persons or entities for the performance of experimental, developmental, or research work in the field of the claimed invention.

* * * * *

■ 5. Section 1.109 is added to read as follows:

§ 1.109 Double patenting.

(a) A double patenting rejection will be made in an application or patent under reexamination if the application or patent under reexamination claims an invention that is not patentably distinct from an invention claimed in a commonly owned patent. This double patenting rejection will be made regardless of whether the application or patent under reexamination and the commonly owned patent have the same or a different inventive entity. A judicially created double patenting rejection may be obviated by filing a terminal disclaimer in accordance with § 1.321(c).

(b) A double patenting rejection will be made in an application or patent under reexamination if the application or patent under reexamination claims an invention that is not patentably distinct

from an invention claimed in a non-commonly owned patent by or on behalf of parties to a joint research agreement in which the inventions claimed in the application or patent under reexamination and in the other patent were made as a result of activities undertaken within the scope of the joint research agreement. This double patenting rejection will be made regardless of whether the application or patent under reexamination and the non-commonly owned patent have the same or a different inventive entity. This double patenting rejection may be obviated by filing a terminal disclaimer in accordance with § 1.321(d).

§ 1.130 [Amended]

■ 6. Section 1.130 is amended by removing and reserving paragraph (b).

■ 7. Section 1.321 is amended by adding a new paragraph (d) to read as follows:

§ 1.321 Statutory disclaimers, including terminal disclaimers.

* * * * *

(d) A terminal disclaimer, when filed in a patent application (rejected application) or in a reexamination proceeding (rejected patent) to obviate a double patenting rejection based upon a patent (disqualified patent) or application (disqualified application) that is not commonly owned but was disqualified under 35 U.S.C. 103(c) as resulting from activities undertaken within the scope of a joint research agreement, must:

(1) Comply with the provisions of paragraphs (b)(2) through (b)(4) of this section;

(2) Be signed in accordance with paragraph (b)(1) of this section if filed in a patent application or be signed in accordance with paragraph (a)(1) of this section if filed in a reexamination proceeding;

(3) Be signed by the patentee or by the applicant, or an attorney or agent of record, of the disqualified patent or application; and

(4) Include a provision that the owner of the rejected application or patent and the owner of the disqualified patent or application each:

(i) Waive the right to separately enforce and the right to separately license the rejected application or patent and the disqualified patent or application;

(ii) Agree that the rejected application or patent and the disqualified patent or application shall be enforceable only for and during such period that the rejected patent or application and the disqualified patent or application are not separately enforced and are not separately licensed; and

(iii) Agree that such waiver and agreement shall be binding upon the owner of the rejected application or patent, its successors, or assigns, and the owner of the disqualified patent or application, its successors, or assigns.

PART 3—ASSIGNMENT, RECORDING AND RIGHTS OF ASSIGNEE

■ 8. The authority citation for 37 CFR part 3 continues to read as follows:

Authority: 15 U.S.C. 1123; 35 U.S.C. 2(b)(2).

■ 9. Section 3.11 is amended by adding a new paragraph (c) to read as follows:

§ 3.11 Documents which will be recorded.

* * * * *

(c) A joint research agreement or an excerpt of a joint research agreement will also be recorded as provided in this part. A joint research agreement or excerpt of a joint research agreement submitted for recording by the Office must include the name of each party to the joint research agreement, the date the joint research agreement was executed, and a concise statement of the field of invention.

■ 10. Section 3.31 is amended by adding a new paragraph (g) to read as follows:

§ 3.31 Cover sheet content.

* * * * *

(g) The cover sheet required by § 3.28 seeking to record a joint research agreement or an excerpt of a joint research agreement as provided by § 3.11(c) must:

(1) Identify the document as a ''joint research agreement'' (in the space provided for the description of the interest conveyed or transaction to be recorded if using an Office-provided form);

(2) Indicate the name of the owner of the application or patent (in the space provided for the name and address of the party receiving the interest if using an Office-provided form);

(3) Indicate the name of each other party to the joint research agreement party (in the space provided for the name of the party conveying the interest if using an Office-provided form); and

(4) Indicate the date the joint research agreement was executed.

Dated: January 4, 2005.

Jon W. Dudas,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 05–461 Filed 1–10–05; 8:45 am]

BILLING CODE 3510–16–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[R05–OAR–2004–IL–0003; FRL–7861–1]

Approval and Promulgation of Air Quality Implementation Plans; Illinois; Withdrawal of Direct Final Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of direct final rule.

SUMMARY: Due to the receipt of an adverse comment, the EPA is withdrawing the November 12, 2004 (69 FR 65378), direct final rule approving a site specific revision to the sulfur dioxide emissions limits for Central Illinois Light Company's Edwards Generating Station in Peoria County, Illinois. The State of Illinois submitted this revision as a modification to the State Implementation Plan for Sulfur Dioxide on July 29, 2003. In the direct final rule, EPA stated that if adverse comments were submitted by December 13, 2004, the rule would be withdrawn and not take effect. On December 13, 2004, EPA received a comment. EPA believes this comment is adverse and, therefore, EPA is withdrawing the direct final rule. EPA will address the comment in a subsequent final action based upon the proposed action also published on November 12, 2004 (69 FR 65394). EPA will not institute a second comment period on this action.

DATES: The direct final rule published at 69 FR 65378 on November 12, 2004 is withdrawn as of January 11, 2005.

FOR FURTHER INFORMATION CONTACT: Mary Portanova, Environmental Engineer, Criteria Pollutant Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, Telephone: (312) 353–5954. E-Mail Address: *portanova.mary@epa.gov*.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements, Sulfur dioxide.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: January 4, 2005.

Norman Niedergang,

Acting Regional Administrator, Region 5.

■ Accordingly, the amendment to 40 CFR 52.720 published in the **Federal Register** on November 12, 2004 (69 FR 65378) on pages