Advisory Panel Meeting transcripts, Gaithersburg, MD, July 22, 1994.

3. K932029, Sofamor Danek TSRH Spinal System.

IV. Environmental Impact

The agency had determined under 21 CFR 25.30(i) that this final rule 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.

V. Analysis of Impacts

FDA has examined the impact of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, this rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The only effect of this correction is to delay the requirement for manufacturers of pedicle screw spinal systems intended for certain uses to submit PMA's for these devices until FDA issues a regulation requiring such submissions. Therefore, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities. This rule also does not trigger the requirement for a written statement under section 202(a) of the Unfunded Mandates Reform Act because it does not impose a mandate that results in an expenditure of $100 million or more by State, local, or tribal governments in the aggregate, or by the private sector, in any one year.

List of Subjects in 21 CFR Part 888

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 888 is amended as follows:

PART 888—ORTHOPEDIC DEVICES

1. The authority citation for 21 CFR part 888 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 888.3070 is revised to read as follows:

§ 888.3070 Pedicle screw spinal system.

(a) *Identification.* Pedicle screw spinal systems are multiple component devices, made from a variety of materials, including alloys such as 316L stainless steel, 316LVM stainless steel, 22Cr-13Ni-5Mn stainless steel, Ti-6Al-4V, and unalloyed titanium, that allow the surgeon to build an implant system to fit the patient's anatomical and physiological requirements. Such a spinal implant assembly consists of a combination of anchors (e.g., bolts, hooks, and/or screws); interconnection mechanisms incorporating nuts, screws, sleeves, or bolts; longitudinal members (e.g., plates, rods, and/or plate/rod combinations); and/or transverse connectors.

(b) *Classification.* (1) Class II (special controls), when intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5–S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis). These pedicle screw spinal systems must comply with the following special controls:

(i) Compliance with material standards;

(ii) Compliance with mechanical testing standards;

(iii) Compliance with biocompatibility standards; and

(iv) Labeling that contains these two statements in addition to other appropriate labeling information:

''Warning: The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5–S1 vertebra, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.''

''Precaution: The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.''

(2) Class III (premarket approval), when intended to provide immobilization and stabilization of spinal segments in the thoracic, lumbar, and sacral spine as an adjunct to fusion in the treatment of degenerative disc disease and spondylolisthesis other than either severe spondylolisthesis (grades 3 and 4) at L5–S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment.

(c)*Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval for the devices described in paragraph (b)(2) of this section. See § 888.3.

Dated: May 11, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–12769 Filed 5–21–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

37 CFR Part 1

[Docket No.: 010202029–1112–02]

RIN 0651–AB35

Revision of Patent Cooperation Treaty Application Procedure; Correction

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Final rule; correction.

SUMMARY: The United States Patent and Trademark Office (Office) published a final rule in the **Federal Register** of March 22, 2001, revising the rules of practice relating to applications filed under the Patent Cooperation Treaty (PCT) to conform the United States rules of practice to the PCT Regulations that became effective on March 1, 2001. This document corrects three errors in that final rule.

EFFECTIVE DATE: March 22, 2001.

FOR FURTHER INFORMATION CONTACT: Charles Pearson, Director, Office of PCT Legal Administration, by telephone at (703) 306–4145; or by mail addressed to: Box PCT, Commissioner for Patents,

Washington, DC 20231; or by facsimile to (703) 308–6459, marked to the attention of Charles Pearson.

SUPPLEMENTARY INFORMATION: The Office published a final rule in the **Federal Register** of March 22, 2001 (66 FR 16004), entitled ''Revision of Patent Cooperation Treaty Application Procedure.'' This document corrects errors in §§ 1.494(c)(2), 1.495(c)(2), and 1.497(a)(1).

Specifically, §§ 1.494(c)(2) and 1.495(c)(2) as revised in the above final rule inadvertently omitted the provisions that:

> The payment of the processing fee set forth in § 1.492(f) is required for acceptance of an English translation later than the expiration of 20 [or 30] months after the priority date. The payment of the surcharge set forth in § 1.492(e) is required for acceptance of the oath or declaration of the inventor later than the expiration of 20 [or 30] months after the priority date. A ''Sequence Listing'' need not be translated if the ''Sequence Listing'' complies with PCT Rule 12.1(d) and the description complies with PCT Rule 5.2(b).

Section 1.497(a)(1) as revised in the above final rule inadvertently omitted the section symbols before the reference to §§ 1.66 or 1.68.

In rule FR Doc. 01–7132, published on March 22, 2001 (66 FR 16004), make the following corrections:

1. On page 16006, in the second column, in § 1.494, in paragraph (c)(2), add the following sentences to the end thereof:

§ 1.494 Entering the national stage in the United States of America as a designated office.

* * * * *

(c) * * *

(2) * * * The payment of the processing fee set forth in § 1.492(f) is required for acceptance of an English translation later than the expiration of 20 months after the priority date. The payment of the surcharge set forth in § 1.492(e) is required for acceptance of the oath or declaration of the inventor later than the expiration of 20 months after the priority date. A ''Sequence Listing'' need not be translated if the ''Sequence Listing'' complies with PCT Rule 12.1(d) and the description complies with PCT Rule 5.2(b).

* * * * *

2. On page 16006, in the third column, in § 1.495, in paragraph (c)(2), add the following sentences to the end thereof:

§ 1.495 Entering the national stage in the United States of America as an elected office.

* * * * *

(c) * * *

(2) * * * The payment of the processing fee set forth in § 1.492(f) is required for acceptance of an English translation later than the expiration of 30 months after the priority date. The payment of the surcharge set forth in § 1.492(e) is required for acceptance of the oath or declaration of the inventor later than the expiration of 30 months after the priority date. A ''Sequence Listing'' need not be translated if the ''Sequence Listing'' complies with PCT Rule 12.1(d) and the description complies with PCT Rule 5.2(b).

* * * * *

1.497 [Corrected]

3. On page 16006, in the third column, in § 1.497, in paragraph (a)(1), line 2, correct ''either 1.66 or 1.68'' to read ''either §§ 1.66 or 1.68''.

Dated: May 15, 2001.

Nicholas P. Godici,

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

[FR Doc. 01–12764 Filed 5–21–01; 8:45 am]

BILLING CODE 3510–16–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MD116–3067a; FRL–6979–6]

Approval and Promulgation of Air Quality Implementation Plans; State of Maryland; Repeal of Petroleum Refinery Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action on a revision to the State of Maryland State Implementation Plan (SIP) submitted on January 4, 2001 by the Maryland Department of the Environment (MDE). This revision repeals the requirements for petroleum refineries in the State of Maryland. There are no petroleum refineries located in the State of Maryland. EPA is approving this SIP in accordance with the requirements of the Clean Air Act.

DATES: This rule is effective on July 23, 2001 without further notice, unless EPA receives adverse written comment by June 21, 2001. If EPA receives such comments, it will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Written comments should be mailed to David L. Arnold, Chief, Air Quality Planning & Information Services Branch, Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. You may inspect copies of the documents relevant to this action during normal business hours at the following locations: Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103; the Air and Radiation Docket and Information Center, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460; and the Maryland Department of the Environment, 2500 Broening Highway, Baltimore, Maryland, 21224.

FOR FURTHER INFORMATION CONTACT: Ellen Wentworth, (215) 814–2034 at the EPA Region III address above, or by e-mail at wentworth.ellen@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Description of the SIP Revision and EPA's Action

The information in this section is organized as follows:

A. What Action Is EPA Taking Today?

EPA is approving a revision to the State of Maryland SIP which was submitted on January 4, 2001 by MDE. This revision repeals Regulation .04, Petroleum Refineries, under Maryland's Code of Maryland Administrative Regulations (COMAR) 26.11.11, Control of Petroleum Products Installations, including Asphalt Paving and Asphalt Concrete Plants. At one time there was the possibility of a petroleum refinery being constructed in the State of Maryland which would have required regulation under COMAR 26.11.11.04, and under Maryland's SIP. However, a facility was never constructed, and at the present time there are no petroleum refineries located in Maryland.

B. Why Is EPA Taking This Action?

EPA is approving this SIP revision at the request of MDE. Since there are no petroleum refineries located in the State of Maryland, Maryland repealed its petroleum refinery regulation, COMAR 26.11.11.04, Petroleum Refineries, under COMAR 26.11.11, Control of Petroleum Products Installations, including Asphalt Paving and Asphalt Concrete Plants. Because there are no oil refineries in the State of Maryland, EPA is approving the SIP revision to amend