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VI. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) 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.

VII. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). 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 proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed 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. Because PMA's for this device could have been required by FDA as early as June 30, 1986, and because firms that distributed this device prior to May 28, 1976, or whose device has been found by FDA to be substantially equivalent will be permitted to continue marketing the implanted mechanical/hydraulic urinary continence device during FDA's review of the PMA or notice of completion of the PDP, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

List of Subjects in 21 CFR Part 876

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 876 be amended as follows:

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

1. The authority citation for 21 CFR part 876 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. Section 876.5280 is amended by revising paragraph (c) to read as follows:

§ 876.5280 Implanted mechanical/hydraulic urinary continence device.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or notice of completion of a PDP is required to be filed with the FDA on or before (insert date 90 days after the effective date of a final rule based on this proposed rule), for any implanted mechanical/hydraulic

urinary continence device that was in commercial distribution before May 28, 1976, or that has on or before (insert date 90 days after the effective date of a final rule based on this proposed rule), been found to be substantially equivalent to the implanted mechanical/hydraulic urinary continence device that was in commercial distribution before May 28, 1976. Any other implanted mechanical/hydraulic urinary continence device shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: January 10, 1995.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 95-3805 Filed 2-14-95; 8:45 am]

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DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Parts 1 and 3

[Docket No. 941120-4320]

RIN 0651-AA76

Changes to Implement 20-Year Patent Term and Provisional Applications

AGENCY: Patent and Trademark Office, Commerce.

ACTION: Proposed rule; change in public hearing location.

SUMMARY: The public hearing scheduled for February 16, 1995, concerning the notice of proposed rulemaking published on December 12, 1994 at 59 FR 63951, with a supplemental request for comments published on January 17, 1995, at 60 FR 3398, will be held in the Roanoke Room, Stouffer Hotel at Crystal City, 2399 Jefferson Davis Highway, Arlington, Virginia, instead of in the Commissioner's Conference Room, Crystal Park 2, Room 912, 2121 Crystal Drive, Arlington, Virginia, as previously indicated. The change in location is being made to accommodate more people.

DATES: Written comments must be submitted on or before February 17, 1995. A public hearing will be held Thursday, February 16, 1995, at 9:30 a.m., in the Roanoke Room, Stouffer Hotel at Crystal City, 2399 Jefferson Davis Highway, Arlington, Virginia. Oral testimony on the effects of patent expiration dates and patent term extension will begin at 1:00 p.m. Requests to present oral testimony should be received on or before February 14, 1995.

ADDRESSES: Address written comments and requests to present oral testimony to the Commissioner of Patents and Trademarks, Washington, DC 20231. Attention: Stephen G. Kunin, Deputy Assistant Commissioner for Patent Policy and Projects, Crystal Park 2, Suite 910, or by fax to (703) 305-8825.

FOR FURTHER INFORMATION CONTACT: Magdalen Y. Greenlief or John F. Gonzales, Special Program Examiners, Office of the Deputy Assistant Commissioner for Patent Policy and Projects, at (703) 305-9285, or by mail marked to their attention and addressed to the Commissioner of Patents and Trademarks, Washington, DC 20231.

Dated: February 9, 1995.

Bruce A. Lehman,

Assistant Secretary of Commerce and Commissioner of Patents and Trademarks.

[FR Doc. 95-3742 Filed 2-14-95; 8:45 am]

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POSTAL SERVICE

39 CFR Part 265

Demands for Testimony or Records in Certain Legal Proceedings

AGENCY: Postal Service.

ACTION: Proposed rule.

SUMMARY: The Postal Service proposes establishing a procedure for Postal Service response to subpoenas or other demands for Postal Service employees to testify about, or produce records concerning, Postal Service matters in private litigation or other proceedings in which the United States is not a party. This proposed rule should minimize the disruption of official duties caused by compliance with those demands, maintain Postal Service control over the release of official information, and otherwise protect the interests of the United States. This proposed rule would prohibit Postal Service employees from complying with those demands without the General Counsel's permission.

DATES: Comments must be received on or before March 17, 1995.

ADDRESSES: Written comments should be mailed or delivered to: Library, Attention Federal Register Comments, U.S. Postal Service, 475 L'Enfant Plaza, SW, Room 11800, Washington, DC 20260-1540. Copies of all written comments will be available for public inspection and photocopying between 8:15 a.m. and 4:45 p.m., Monday through Friday, in Room 11800 at the above address.

FOR FURTHER INFORMATION CONTACT: Julie A. Holvik, Attorney, (312) 765-5230.

SUPPLEMENTARY INFORMATION: The proposed rule provides that, in response to subpoenas or other demands for testimony or records concerning Postal Service matters in private litigation or other proceedings in which the United States is not a party, Postal Service employees may testify or produce records only if the General Counsel or the General Counsel's delegate authorizes compliance with the demand. In making this determination, the General Counsel or his or her delegate will consider whether compliance is in accordance with applicable laws, privileges, rules, authority, and regulations and would not be contrary to the interests of the United States.

Several federal agencies have enacted this type of regulation, including the Department of Justice, the Department of Transportation, and the Department of Veterans Affairs. The courts have recognized the authority of federal agencies to limit compliance with demands in this manner. *See, United States ex. rel. Touhy v. Ragen*, 340 U.S. 462 (1951). Moreover, subpoenas by state courts, legislatures, or legislative committees that attempt to assert jurisdiction over federal agencies are inconsistent with the Supremacy Clause of the U.S. Constitution, and a federal regulation regarding compliance with those subpoenas reinforces this principle. *See, McCulloch v. Maryland*, 17 U.S. (4 Wheat.) 316 (1819); *United States v. McLeod*, 385 F.2d 734 (5th Cir. 1967).

This proposed rule would not apply to situations in which the United States is a party in a lawsuit. It also would not apply to instances in which an employee is requested to appear in legal proceedings unrelated to federal activities or the employee's duties at the Postal Service. Finally, the proposed rule would not apply to subpoenas or requests for information submitted by either House of Congress or by a congressional committee or subcommittee with jurisdiction over the matter for which the testimony or information is requested.

List of Subjects in 39 CFR Part 265

Administrative practice and procedure, Government employees, Release of information.

For the reasons set out in this notice, 39 CFR part 265 is proposed to be amended as follows.

PART 265—RELEASE OF INFORMATION

1. The authority citation for part 265 is revised to read as follows:

Authority: 39 U.S.C. 401, 403, 410, 1001, 2601; 5 U.S.C. 552; Inspector General Act of 1978, as amended (Pub. L. 95-452, as amended, 5 U.S.C. App. 3).

2. Section 265.12 is added to read as follows:

§ 265.12 Demands for testimony or records in certain legal proceedings.

(a) *Scope and applicability of this section.* (1) This section establishes procedures to be followed if the Postal Service or any Postal Service employee receives a demand for testimony concerning or disclosure of:

(i) Records contained in the files of the Postal Service; or

(ii) Information relating to records contained in the files of the Postal Service; or

(iii) Information or records acquired or produced by the employee in the course of his or her official duties or because of the employee's official status.

(2) This section does not create any right or benefit, substantive or procedural, enforceable by any person against the Postal Service.

(3) This section does not apply to any of the following:

(i) Any legal proceeding in which the United States is a party;

(ii) A demand for testimony or records made by either House of Congress or, to the extent of matter within its jurisdiction, any committee or subcommittee of Congress; or

(iii) An appearance by an employee in his or her private capacity in a legal proceeding in which the employee's testimony does not relate to the employee's official duties or the functions of the Postal Service; or

(iv) A demand for testimony or records submitted to the Postal Inspection Service (a demand for Inspection Service records or testimony will be handled in accordance with rules published at § 265.11).

(4) This section does not exempt a request from applicable confidentiality requirements, including the requirements of the Privacy Act. 5 U.S.C. 552a.

(b) *Definitions.* The following definitions apply to this section:

(1) *Adjudicative authority* includes, but is not limited to, the following:

(i) A court of law or other judicial forums, whether local, state, or federal; and

(ii) Mediation, arbitration, or other forums for dispute resolution.

(2) *Demand* includes a subpoena, subpoena duces tecum, request, order,