features, data sets from bench studies and clinical trials, other relevant performance data, and labeling will ensure that acceptable levels of performance for both safety and effectiveness are addressed before marketing clearance. Thus, persons who intend to market this device type must submit to FDA a premarket notification submission containing information on the TACHAS they intend to market prior to marketing the device.

On August 20, 2002, FDA issued an order classifying the RetroX device and substantially equivalent devices of this generic type into class II under the generic name, transcutaneous air conduction hearing aid system. FDA identifies this generic type of device as:

A wearable sound-amplifying device intended to compensate for impaired hearing without occluding the ear canal. The device consists of an air conduction hearing aid attached to a surgically fitted tube system, which is placed through soft tissue between the post auricular region and the outer ear canal.

The order also identifies a special control applicable to this device a guidance document entitled ''Class II Special Controls Guidance Document: Transcutaneous Air Conduction Hearing Aid System (TACHAS); Guidance for Industry and FDA.'' Any firm submitting a 510(k) premarket notification for the device would need to address the issues covered in the special control guidance. However, the firm would need to show only that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

FDA is now codifying the classification and the special control by adding new § 874.3950. For the convenience of the reader, FDA is also adding a new § 874.1(e) to inform the reader where to find guidance documents referenced in 21 CFR part 874.

II. Environmental Impact

The agency has determined under 21 CFR 25.34(b) 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.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, and the Regulatory Flexibility Act (5 U.S.C. 601–612), 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 final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the final rule is not a significant regulatory action as defined by the Executive order and so it 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. FDA knows of only one manufacturer of this type of device. Classification of these devices from class III to class II will relieve manufacturers of the device of the cost of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs. The agency, therefore, certifies that the final rule will not have a significant impact on a substantial number of small entities. In addition, this final rule will not impose costs of $100 million or more on either the private sector or State, local, and tribal governments in the aggregate and, therefore, a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act is not required.

IV. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

V. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects in 21 CFR Part 874

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 874 is amended as follows:

PART 874—EAR, NOSE, AND THROAT DEVICES

1. The authority citation for 21 CFR part 874 continues to read as follows:

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

2. Section 874.1 is amended by adding paragraph (e) to read as follows:

§ 874.1 Scope.

* * * * *

(e) Guidance documents referenced in this part are available on the Internet at http://www.fda.gov/cdrh/guidance.html

3. Section 874.3950 is added to subpart D to read as follows:

§ 874.3950 Transcutaneous air conduction hearing aid system.

(a) *Identification.* A transcutaneous air conduction hearing aid system is a wearable sound-amplifying device intended to compensate for impaired hearing without occluding the ear canal. The device consists of an air conduction hearing aid attached to a surgically fitted tube system, which is placed through soft tissue between the post auricular region and the outer ear canal.

(b) *Classification.* Class II (special controls). The special control for this device is FDA's guidance document entitled ''Class II Special Controls Guidance Document: Transcutaneous Air Conduction Hearing Aid System (TACHAS); Guidance for Industry and FDA.'' See § 874.1 for the availability of this guidance document.

Dated: October 28, 2002.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 02–28398 Filed 11–6–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Parole Commission

28 CFR Part 2

Paroling, Recommitting, and Supervising Federal Prisoners: Prisoners Serving Sentences Under the United States and District of Columbia Codes

AGENCY: United States Parole Commission, Justice.

ACTION: Interim rule with request for comment.

SUMMARY: The U.S. Parole Commission is amending its procedures governing the mandatory release of military prisoners confined in federal civilian prisons. Such mandatory release is earned through good time credits. The amendment implements a Department of Defense Instruction that permits the U.S. Parole Commission to place a military prisoner who is released from a federal civilian prison under ''mandatory supervision as if on parole'' until the expiration of the sentence imposed, if the Commission determines that such supervision is necessary for the orderly transition of the offender back into community.

DATES: *Effective Date:* These rule amendments are effective December 9, 2002.

Comment Date: Comments must be received by December 23, 2002.

ADDRESSES: Send comments to the Office of General Counsel, U.S. Parole Commission, 5550 Friendship Blvd., Chevy Chase, Maryland 20815.

FOR FURTHER INFORMATION CONTACT: Office of General Counsel, U.S. Parole Commission, 5550 Friendship Blvd., Chevy Chase, Maryland 20815, telephone (301) 492–5959. Questions about this publication are welcome, but inquiries concerning individual cases cannot be answered over the telephone.

SUPPLEMENTARY INFORMATION: Former Department of Defense regulations did not permit any military prisoner who was released by operation of law due to good time credits to be subject to supervision in the community for the remainder of the imposed sentence. This was in contrast to the requirement that applies to federal civilian prisoners who are eligible for but denied parole. Prisoners sentenced by military courts martial and then transferred to a federal institution come under the exclusive jurisdiction of the U.S. Parole Commission for parole purposes pursuant to 10 U.S.C. 858. Thus, in the absence of any rule authorizing post-release supervision for military mandatory releasees, there was a gap in the Commission's authority to require post-release supervision for military prisoners mandatorily released on good time from institutions operated by the Federal Bureau of Prisons. (The Bureau of Prisons considered former 18 U.S.C. 4164—which authorizes mandatory release supervision for federal civilian prisoners eligible for parole—to be inapplicable to military prisoners who committed their crimes on or after November 1, 1987.) Thus, if the Commission denied parole and continued a military prisoner to the expiration of his sentence, the Commission was not able to supervise the offender. However, if the Commission paroled the military prisoner prior to the mandatory release date, the Commission could supervise the military offender just as any other parolee to the expiration of the prisoner's sentence.

At the request of the Attorney General of the United States, the Department of Defense has amended its regulations regarding the mandatory release of military prisoners, including prisoners in the custody of the Bureau of Prisons. *See* DoD Instruction 1325.7, ''Administration of Military Correctional Facilities and Clemency and Parole Authority,'' July 17, 2001. These regulations generally allow for the supervision of military prisoners mandatorily released with good time deductions.[1] In the regulations, the Department of Defense adopted a policy to use mandatory supervision in all cases except where the Service Clemency and Parole Boards find it inappropriate. The regulations also permit the Parole Commission to place military prisoners who are in federal civilian custody on ''mandatory supervision'' after they are mandatorily released, if the Commission finds that such supervision is appropriate ''to provide an orderly transition to civilian life for released prisoners and to protect the communities into which the prisoners are released.'' *See* DoD Instruction 1325.7 (6.20.8). However, the DoD Instruction is silent as to whether the Commission should, as the Department of Defense has done, adopt a general presumption that mandatory supervision is appropriate. Additionally, the new DoD instruction may be applied only to offenders who committed their crimes 30 days or more after the rule change. Therefore, under the terms of the DoD instruction, the Commission can only require supervision if the prisoner committed his crime on or after August 16, 2001.

The Commission is adopting a paragraph at the end of 28 CFR 2.35 so that the Commission's rules will conform to the Department of Defense regulations and policy regarding the mandatory release of military prisoners. Pursuant to the DoD Instruction, the amended rule states that when the Commission orders a military offender continued to expiration, the military prisoner will be placed on ''mandatory supervision'' until the expiration of his sentence if the Commission finds that the DoD criteria are met. The Commission is adopting this rule in order to give military offenders incarcerated in federal civilian prisons notice that, if the Commission denies the prisoner parole and continues the prisoner to the expiration of the prisoner's sentence, the prisoner may be required to serve a period of mandatory supervision after the prisoner's release. Although the Commission already has the authority under Department of Defense regulations to order mandatory supervision for military prisoners who committed their offenses on or after August 16, 2001, this rule further clarifies the Commission's authority and explains the Commission's general statement of policy regarding mandatory supervision.

The amended rule also includes the presumption that supervision is appropriate for all military mandatory releasees unless case-specific factors indicate that supervision is not appropriate. *See* DoD Instruction 1325.7 (6.20.1). The Commission is adopting this presumption for several reasons. First, the presumption in favor of supervision conforms with the presumption in the DoD Instruction. The inclusion of the presumption in favor of supervision after mandatory release will thus result in a uniform application of the Instruction among military offenders released from military and civilian institutions. Most importantly, the Commission agrees with the Department of Defense's general assessment that supervision in the community is, for the majority of cases, a highly effective technique to provide for a transition into the community and to protect the communities into which the prisoners are released. Therefore, the rule states that mandatory supervision shall be presumed unless the Commission finds case-specific factors illustrating that such supervision is inappropriate.

Finally, the rule makes it clear that, a prisoner on ''mandatory supervision'' will be subject to the conditions of parole at 28 CFR 2.40 and will be eligible for early termination of the supervision under 28 CFR 2.43. Thus, under the rule, military prisoners released on mandatory supervision will be subject to the same conditions and will have the same prospect for early termination of their supervision as federal offenders under parole or mandatory supervision.

[1] Mandatory supervision for military offenders differs from mandatory release for ''old law'' U.S. Code offenders under 18 U.S.C. 4164 since such supervision runs to the full term without the 180 -day reduction that applies to civilian, ''old law'' mandatory releasees.

Implementation

This interim rule will be implemented for any military offender mandatorily released on good time deductions from a federal civilian prison if the offender committed his offense after August 15, 2001.

Regulatory Assessment Requirements

The U.S. Parole Commission has determined that this interim rule does not constitute a significant rule within the meaning of Executive Order 12866. The interim rule will not have a significant economic impact upon a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 605(b), and is deemed by the Commission to be a rule of agency practice that does not substantially affect the rights or obligations of non-agency parties pursuant to Section 804(3)(c) of the Congressional Review Act.

List of Subjects in 28 CFR Part 2

Administrative practice and procedure, Prisoners, Probation and Parole.

The Amended Rule

Accordingly, the U.S. Parole Commission is adopting the following amendments to 28 CFR Part 2.

PART 2—[AMENDED]

1. The authority citation for 28 CFR Part 2 continues to read as follows:

Authority: 18 U.S.C. 4203(a)(1) and 4204(a)(6).

Subpart A—United States Code Prisoners and Parolees

2. Section 2.35 is amended by adding the following paragraph (d):

§ 2.35 Mandatory release in the absence of parole.

* * * * *

(d) If the Commission orders a military prisoner who is under the Commission's jurisdiction for an offense committed after August 15, 2001 continued to the expiration of his sentence (or otherwise does not grant parole), the Commission shall place such prisoner on mandatory supervision after release if the Commission determines that such supervision is appropriate to provide an orderly transition to civilian life for the prisoner and to protect the community into which such prisoner is released. The Commission shall presume that mandatory supervision is appropriate for all such prisoners unless case-specific factors indicate that supervision is inappropriate. A prisoner who is placed on mandatory supervision shall be deemed to be released as if on parole, and shall be subject to the conditions of release at § 2.40 until the expiration of the maximum term for which he was sentenced, unless the Commission terminates the supervision early under § 2.43.

Dated: October 31, 2002.

Edward F. Reilly, Jr.,

Chairman, U.S. Parole Commission.

[FR Doc. 02–28318 Filed 11–6–02; 8:45 am]

BILLING CODE 4410–31–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 3

RIN 2900–AL20

Service Connection by Presumption of Aggravation of a Chronic Preexisting Disease

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This document amends the Department of Veterans Affairs (VA) adjudication regulations concerning presumptive service connection to reflect a statutory presumption that a chronic disease that preexisted the veteran's entry into military service but was first manifest to a 10-percent degree of disability within a specified period after service was aggravated by the veteran's military service. This amendment is necessary to make the regulations conform with the statute and the Court's decision.

DATES: *Effective Date:* November 7, 2002.

FOR FURTHER INFORMATION CONTACT: John Bisset, Jr., Consultant, Regulations Staff, Compensation and Pension Service, Veterans Benefits Administration, 810 Vermont Avenue, NW., Washington, DC 20420, telephone (202) 273–7213.

SUPPLEMENTARY INFORMATION: Section 1112(a), 38 U.S.C., states that, ''a chronic disease becoming manifest to a degree of 10 percent or more within one year from the date of separation from such service * * * shall be considered to have been incurred in or aggravated by such service, notwithstanding there is no record of evidence of such disease during the period of service.''

In the VA General Counsel Precedent Opinion 14–98 (VAOPGCPREC 14–98 (October 2, 1998)), the General Counsel held that Section 1112(a) of title 38, United States Code, does not establish a presumption of aggravation for a chronic disease that existed prior to service but first became manifest to a compensable degree within the presumptive period following service.

In *Splane* v. *West*, 216 F. 3d 1058 (2000), the United States Court of Appeals for the Federal Circuit concluded, among other things, that the General Counsel's interpretation of 38 U.S.C. 1112(a) was not in accordance with law and was therefore in excess of statutory authority. The Court held that 38 U.S.C. 1112(a) establishes not only a presumption of service incurrence for chronic diseases first manifest after service, but also a presumption of aggravation for chronic diseases that existed prior to service but first became manifest to a degree of disability of 10 percent or more within the presumption period after service. The Court vacated that portion of the General Counsel Precedent Opinion which interpreted 38 U.S.C. 1112(a).

VA regulations currently prohibit establishing service connection for aggravation of a preexisting chronic disease that first becomes manifest to a degree of 10 percent or more following discharge from military service. This prohibition is inconsistent with the statute as interpreted by the United States Court of Appeals for the Federal Circuit. Therefore, we are amending 38 CFR 3.307(a), (c), (d), and 3.309(a), to conform to the plain language of the statute and the conclusions of the Court.

Presently, 38 CFR 3.307(a), (c), and (d) provide only for a presumption of service incurrence. Accordingly, it is necessary to revise those paragraphs to include a presumption of aggravation.

38 CFR 3.307(d) currently states the factors to be considered in determining whether the presumption of service incurrence has been rebutted. The current regulation is based on the invalid conclusion that the presumption is one of service incurrence only. This provision is inconsistent with *Splane* because *Splane* establishes that 38 U.S.C. 1112(a) includes a presumption of aggravation of pre-existing diseases that were not incurred in service. Accordingly, it is necessary to revise 38 CFR 3.307(d) to state separately the criteria for rebutting the presumption of service incurrence (in cases where the chronic disease did not exist prior to service) and the criteria for rebutting the presumption of aggravation (in cases where the chronic disease did exist prior to service).

A current VA regulation, 38 CFR 3.306(a), provides that a presumption of aggravation based on an increase in the severity of a preexisting condition during service may be rebutted by evidence that the increase was due to