FDA expects that only two manufacturers will submit a PMA or PDP for the penile inflatable implant. FDA does not believe that two companies are a significant number of small entities. FDA estimates that it costs up to $1 million to develop and submit a PMA or PDP for this type of device. As noted previously, the penile inflatable implant was classified into class III on November 23, 1983, and FDA published a proposed rule to require a PMA or PDP for this device on April 28, 1993. Thus, manufacturers have long been aware of the need to develop information in support of a PMA or a PDP. The cost of developing the data, therefore, has been spread over the past several years. Moreover, since the publication of the proposed rule, FDA has been working closely with both manufacturers to assist them in preparing for the submission of a PMA or a PDP, and one has successfully completed a PDP for two device models. FDA estimates based on such information as is publicly available, that these two companies have annual revenues in excess of several hundred million dollars. FDA, therefore, believes that this final rule will not be an undue burden on these manufacturers. The agency therefore certifies that the final 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.

VII. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3530). The burden hours required for § 876.3350(c) are reported and approved under OMB Control No. 0910–0231.

VIII. References

The following references have been placed on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. These references may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

1. Barrett, D. M., D. C. O'Sullivan, A. A. Maliza, H. M. Reiman, and P. C. Abell-Aleff, ''Particle Shedding and Migration From Silicone Genitourinary Prosthetic Devices,'' *The Journal of Urology*, 146:319–322, 1991.

2. Fishman, I. J. and F. N. Flores, ''Retrospective Review of Pelvic Lymph Nodes in Patients with Previously Implanted Silicone Penile Prosthesis,'' *The Journal of Urology*, 149:355A, 1993.

3. Hennekens, C. H., I. Lee, N. Cook, P. R. Hebert, E. W. Karlson, F. LaMotte, J. E. Manson, and J. E. Buring, ''Self-reported Breast Implants and Connective-Tissue Diseases in Female Health Professionals,'' *Journal of the American Medical Association*, 275:616–621, 1996.

4. Silverman, B. G., S. L. Brown, R. A. Bright, R. G. Kaczmarek, J. B. Arrowsmith-Lowe, and D. A. Kessler, ''Reported Complications of Silicone Gel Breast Implants: An Epidemiologic Review,'' *Annals of Internal Medicine*, 124:744–756, 1996.

5. Institute of Medicine, ''Safety of Silicone Breast Implants,'' National Academy Press, Washington, DC, 1999.

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, 21 CFR part 876 is amended as follows:

PART 876—GASTROENTEROLOGY–UROLOGY DEVICES

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

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

2. Section 876.3350 is amended by revising paragraph (c) to read as follows:

§ 876.3350 Penile inflatable implant.

* * * * *

(c) *Date premarket approval application (PMA) or notice of completion of a product development protocol (PDP) is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before July 11, 2000, for any penile inflatable implant that was in commercial distribution before May 28, 1976, or that has, on or before July 11, 2000, been found to be substantially equivalent to a penile inflatable implant that was in commercial distribution before May 28, 1976. Any other penile inflatable implant shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

Dated: March 24, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00–9002 Filed 4–11–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 8

RIN 2900–AJ78

National Service Life Insurance

AGENCY: Department of Veterans Affairs.

ACTION: Final rule; technical amendment.

SUMMARY: This document amends the Department of Veterans Affairs regulations regarding payments of premiums for National Service Life Insurance by correcting cross-references.

DATES: *Effective date:* April 12, 2000.

FOR FURTHER INFORMATION CONTACT: Ms. Jeanne Derrick, Attorney-Advisor, Department of Veterans Affairs Regional Office and Insurance Center, P.O. Box 8079, Philadelphia, Pennsylvania 19101, telephone number (215) 842–2000, ext. 4277, fax number (215) 381–3504.

SUPPLEMENTARY INFORMATION: In a final rule published in the **Federal Register** on February 15, 2000 (65 FR 7437), VA redesignated certain sections in 38 CFR part 8. This document makes changes regarding cross-references to reflect these redesignations.

Since this document makes only non-substantive changes, we are dispensing with prior notice and comment and delayed effective date provisions of 5 U.S.C. 552 and 553.

The Catalog of Federal Domestic Assistance Program number for this regulation is 64.103.

List of Subjects in 38 CFR Part 8

Disability benefits, Life insurance, Loan programs-veterans, Military personnel, Veterans.

Approved: April 6, 2000.

Thomas O. Gessel,

Director, Office of Regulations Management.

Accordingly, 38 CFR part 8 is corrected by making the following correcting amendments:

PART 8—NATONAL SERVICE LIFE INSURANCE

1. The authority citation for part 8 continues to read as follows:

Authority: 38 U.S.C. 501, 1901–1929, 1981–1988, unless otherwise noted.

§ 8.3 [Amended]

2. In § 8.3(a)(5), remove ''(§ 8.9)'' and add, in its place, ''(§ 8.2(d))''.

3. In § 8.3(a)(7), remove ''(§ 8.17)'' and add, in its place, ''(§ 8.14)''.

4. In § 8.3(b)(3), remove ''(§ 8.17)'' and add, in its place, ''(§ 8.14)''.

§ 8.6 [Amended]

5. In § 8.6, remove ''§§ 8.3, 8.4 or 8.5'' and add, in its place, ''§§ 8.2 or 8.3''.

§ 8.7 [Amended]

6. In § 8.7(a), remove ''§ 8.11'' and add, in its place, ''§ 8.8''.

§ 8.9 [Amended]

7. In § 8.9, remove ''§ 8.11'' and add, in its place, ''§ 8.8''; and, in both places it appears, remove ''§ 8.11(a)'' and add, in its place, ''§ 8.8(a)''.

§ 8.10 [Amended]

8. In § 8.10(g), remove ''§§ 8.17 and 8.18'' and add, in its place, ''§§ 8.14 and 8.15''.

§ 8.11 [Amended]

9. In § 8.11(a), remove ''§ 8.17(b)'' and add, in its place, ''§ 8.14(b)''.

§ 8.24 [Amended]

10. In § 8.24, remove ''§ 8.25'' and add, in its place, ''§ 8.22''.

[FR Doc. 00–9035 Filed 4–11–00; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 131

[FRL–6576–2]

Withdrawal of Certain Federal Human Health and Aquatic Life Water Quality Criteria Applicable to Rhode Island, Vermont, the District of Columbia, Kansas and Idaho

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: In 1992, EPA promulgated Federal regulations establishing water quality criteria for toxic pollutants for several States, including Rhode Island, Vermont, the District of Columbia, Kansas and Idaho. These States have now adopted, and EPA has approved, human health and aquatic life water quality criteria. In this action, EPA is amending the Federal regulations to withdraw certain human health and aquatic life criteria applicable to these States. EPA is withdrawing its criteria applicable to these States without a notice and comment rulemaking because the States' adopted criteria are no less stringent than the Federal criteria.

DATES: This rule is effective April 12, 2000.

ADDRESSES: The administrative record for consideration of Rhode Island and Vermont's criteria is available for public inspection at EPA Region 1, Office of Water, 1 Congress Street, Suite 1100, Boston MA 02114–1505 during normal business hours of 9:00 a.m. to 5:00 p.m. The administrative record for consideration of the District of Columbia human health criteria is available at EPA Region 3, Water Protection Division, 1650 Arch St, Philadelphia PA 19103–2029 during normal business hours of 9:00 am to 5:00 pm. The administrative record for consideration of Kansas's human health and aquatic life criteria is available for public inspection at EPA Region 7, Water Resources Protection Branch, 901 North 5th Street, Kansas City, Kansas 66101 during normal business hours of 8:00 a.m. to 4:30 p.m. The administrative record for consideration of Idaho's aquatic life criteria is available for public inspection at EPA Region 10, Office of Water, 1200 Sixth Avenue, Seattle, Washington 98101 during normal business hours of 8:00 a.m. to 4:30 p.m

FOR FURTHER INFORMATION CONTACT: Thomas J. Gardner at EPA Headquarters, Office of Water (4305), 1200 Pennsylvania Ave NW, Washington, D.C., 20460 (tel: 202–260–7309). For questions regarding Rhode Island and Vermont, contact Bill Beckwith in EPA's Region 1 at 617–918–1544. For questions regarding the District of Columbia, contact Garrison Miller in EPA's Region 3 at 215–814–5745. For questions regarding Kansas, contact Ann Jacobs in EPA's Region 7 at 913–551–7930. For questions regarding Idaho, contact Lisa Macchio in EPA's Region 10 at 206–553–1834.

SUPPLEMENTARY INFORMATION:

Potentially Affected Entities

Citizens concerned with water quality in Rhode Island, Vermont, Kansas, the District of Columbia and Idaho may be interested in this rulemaking. Entities discharging toxic pollutants to waters of the United States in these States could be affected by this rulemaking since criteria are used in determining NPDES permit limits. Potentially affected categories and entities include:

Category	Examples of potentially affected entities
Industry	Industries discharging toxic pollutants to surface waters in Rhode Island, Vermont, District of Columbia, Kansas and Idaho.
Municipalities	Publicly-owned treatment works discharging toxic pollutants to surface waters in Rhode Island, Vermont, District of Columbia, Kansas and Idaho.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be potentially affected by this action. This table lists the types of entities that EPA is now aware could potentially be affected by this action. Other types of entities not listed in the table could also be affected. To determine whether your facility is affected by this action, you should carefully examine the applicability criteria in § 131.36 of title 40 of the Code of Federal Regulations. If you have any questions regarding the applicability of this action to a particular entity, consult the appropriate person(s) listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

Background

In 1992, EPA promulgated a final rule (known as the ''National Toxics Rule'', or ''NTR'') to establish numeric water quality criteria for 12 States and two Territories (hereafter ''States'') that had failed to comply fully with section 303(c)(2)(B) of the Clean Water Act (''CWA'') (57 FR 60848). The criteria, codified at 40 CFR 131.36, became the applicable water quality standards in those 14 jurisdictions for all purposes and programs under the CWA effective February 5, 1993.

When a State adopts criteria that meet the requirements of the CWA, EPA will issue a rule amending the NTR to withdraw its criteria. Section 553 of the Administrative Procedure Act, U.S.C. 533(b)(B) provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary or contrary to the public interest, the agency may issue a rule without providing notice and opportunity for public comment. EPA has determined that there is good cause for making today's rule final without prior proposal and opportunity for comment because EPA has determined that, if the State's criteria are no less stringent than the Federal regulations, additional comment on the criteria is unnecessary. EPA finds that this constitutes good cause for issuing this final rule without notice and comment. EPA has determined that the States criteria are no less stringent than the