Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 94–NM–199–AD." The postcard will be date stamped and returned to the commenter.

The regulations adopted herein will not 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. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and that it is not a "significant regulatory action" under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption ADDRESSES.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

94–25–02 Jetstream Aircraft Limited (Formerly British Aerospace Commercial Aircraft Limited): Amendment 39–9086. Docket 94–NM–199–AD.

Applicability: Model ATP airplanes having constructor's numbers 2002 through 2063, inclusive; and equipped with Normalair-Garrett Limited oil coolers having part number 8248C000, 8439C000, or 8714C000; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must use the authority provided in paragraph (c) to request approval from the FAA. This approval may address either no action, if the current configuration eliminates the unsafe condition; or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any airplane from the applicability of this AD.

Compliance: Required as indicated, unless accomplished previously.

To prevent loss of engine oil that may lead to a forced shutdown of the engine, accomplish the following:

(a) Prior to the accumulation of 2,000 total landings on the engine oil cooler that is cooled by ram air on the left and right engine, or within 50 hours time-in-service after the effective date of this AD, whichever occurs later, perform a detailed visual inspection to detect cracking in the oil cooler, in accordance with British Aerospace Service Bulletin ATP–79–23, dated August 26, 1994.

(1) If no cracking is detected, repeat this inspection thereafter at intervals not to exceed 75 hours time-in-service.

(2) If any cracking is detected, prior to further flight, replace the oil cooler with a serviceable oil cooler having either part number (P/N) 8439C000–002 or 8714C000–002, in accordance with British Aerospace Service Bulletin ATP–79–23, dated August 26, 1994, or with an oil cooler than has been reworked and re-identified in accordance with British Aerospace Service Bulletin ATP–79–24–10360A, dated September 4, 1994.

(b) Installation of an oil cooler that has been reworked and re-identified as either P/N 8714C000–002 or 8439C000–002, in accordance with British Aerospace Service Bulletin ATP–79–24–10360A, dated September 4, 1994, constitutes terminating action for the inspection requirements of this AD.

Note 2: Reworked oil coolers have an initial life limit of 9,000 landings. This life limit and any changes to it are specified in the Limitations Section in Chapter 5 of the ATP Maintenance Manual.

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Standardization Branch, ANM–113.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch, ANM–113.

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(e) The inspection shall be done in accordance with Jetstream Service Bulletin ATP–79–23, dated August 26, 1994, and the rework and re-identification shall be done in accordance with Jetstream Service Bulletin ATP–79–24–10360A, dated September 4, 1994. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Jetstream Aircraft, Inc., P.O. Box 16029, Dulles International Airport, Washington, DC. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(f) This amendment becomes effective on December 22, 1994.

Issued in Renton, Washington, on November 30, 1994.

James V. Devany,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 94–29918 Filed 12–6–94; 8:45 am]

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14 CFR Part 39

[Docket No. 94–NM–207–AD; Amendment 39–9085; AD 94–25–01]

Airworthiness Directives; Boeing Model 747 Series Airplanes Equipped with Pratt & Whitney Model JT9D–70 Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that is applicable to certain Model 747 series airplanes. This action requires inspections to detect cracking of the surfaces of the outboard strut spring beam, and replacement of cracked spring beams. It also requires an inspection to detect damage to the structure that is adjacent to the cracked spring beam, and replacement of any cracked parts. This amendment is prompted by a report of failure of a spring beam due to cracking that was propagated by fatigue. The actions specified in this AD are intended to prevent failure of a spring beam, which could lead to loss of an outboard strut.

DATES: Effective on December 22, 1994.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of December 22, 1994.

Comments for inclusion in the Rules Docket must be received on or before February 6, 1995.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 94–NM–207–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

The service information referenced in this AD may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Tim Backman, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Transport Airplane Directorate, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (206) 227–2776; fax (206) 227–1181.

SUPPLEMENTARY INFORMATION: Recently, the FAA received a report that the spring beam on a Boeing Model 747–200 series airplane equipped with Pratt & Whitney (P&W) Model JT9D–70 engines was severed (failed) forward of the mid pivot bolt housing at the outboard spring beam on the number 4 outboard strut. Investigation revealed that cracking initiated at a flaw (porosity) in the material of the spring beam and propagated due to fatigue. The subject airplane was operated as a freighter and had accumulated 15,809 total flight cycles on the struts. This airplane was originally delivered with P&W Model JT9D–3 engines and struts, but was later reconfigured with P&W Model JT9D–70 engines and struts.

Spring beams are used in place of midspar fittings on the outboard struts of all Model 747 series airplanes, except those equipped with P&W Model JT9D–3 and –7 engines. (The P&W Model JT9D–3 and –7 engines have midspar fittings at the outboard strut.) Airplanes equipped with P&W Model JT9D–70 engines have spring beams that are made of titanium. All other spring beams are made of steel, which analyses and tests have shown to be more resistant to fatigue cracking than titanium spring beams.

Fatigue cracking, if not corrected, could result in failure of a spring beam, which could lead to the loss of an outboard strut.

The FAA has reviewed and approved Boeing Alert Service Bulletin 747–54A2171, dated October 31, 1994, which describes procedures for repetitive detailed visual inspections to detect cracking of the upper, lower, and side surfaces of the spring beam, and replacement of cracked spring beams with new spring beams.

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design, this AD is being issued to prevent failure of a spring beam due to fatigue cracking, which could lead to the loss of an outboard strut. This AD requires repetitive detailed visual inspections to detect cracking of the surfaces of the spring beam from the root of the clevis lugs to the forward journal, and replacement of cracked spring beams with new spring beams. This AD also requires an additional detailed visual inspection to detect damage of the adjacent spring beam and all support fittings of the affected strut, and replacement of any cracked parts with new parts. The actions are required to be accomplished in accordance with the alert service bulletin described previously.

As an alternative to the repetitive detailed visual inspections, this AD also provides for an optional terminating action, which entails removing the spring beam, accomplishing a fluorescent dye penetrant inspection, and accomplishing a zero-time overhaul of the spring beam, in accordance with Section 54–00–01 of the Boeing Overhaul Manual, and reinstalling that spring beam.

As a result of recent communications with the Air Transport Association (ATA) of America, the FAA has learned that, in general, some operators may misunderstand the legal effect of AD's on airplanes that are identified in the applicability provision of the AD, but that have been altered or repaired in the area addressed by the AD. The FAA points out that all airplanes identified in the applicability provision of an AD are legally subject to the AD. If an airplane has been altered or repaired in the affected area in such a way as to affect compliance with the AD, the owner or operator is required to obtain FAA approval for an alternative method of compliance with the AD, in accordance with the paragraph of each AD that provides for such approvals. A note has been included in this rule to clarify this requirement.

Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and opportunity for prior public comment hereon are impracticable, and that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES**. All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following

statement is made: "Comments to Docket Number 94–NM–207–AD." The postcard will be date stamped and returned to the commenter.

The regulations adopted herein will not 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. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and that it is not a "significant regulatory action" under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption ADDRESSES.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

94–25–01 Boeing: Amendment 39–9085. Docket 94–NM–207–AD.

Applicability: Model 747 series airplanes having line numbers 202 through 396 inclusive, equipped with Pratt & Whitney Model JT9D–70 engines, certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must use the authority provided in paragraph (c) to request approval from the FAA. This approval may address either no action, if the current configuration eliminates the unsafe condition; or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any airplane from the applicability of this AD.

Compliance: Required as indicated, unless accomplished previously.

To prevent failure of a spring beam, which could lead to the loss of an outboard strut, accomplish the following:

(a) Prior to the accumulation of 10,000 total flight cycles or within 30 days after the effective date of this AD, whichever occurs later, perform a detailed visual inspection to detect cracking of the upper, lower, and side surfaces of the spring beam from the root of the clevis lugs to the forward journal, in accordance with Boeing Alert Service Bulletin 747–54A2171, dated October 31, 1994. (Remove the gap covers and fairing access panels to perform this inspection.)

Note 2: The area of inspection is illustrated in Figure 3 of the service bulletin.

(1) If no cracking is detected, repeat the inspection thereafter at intervals not to exceed 300 flight cycles.

(2) If any cracking is detected, prior to further flight, accomplish the requirements of paragraphs (a)(2)(i), (a)(2)(ii), and (a)(2)(iii) of this AD, in accordance with the service bulletin.

(i) Replace the cracked spring beam with a new spring beam.

(ii) Perform the detailed visual inspection required by paragraph (a) of this AD to detect cracking of the other spring beam on the affected strut. Also perform a detailed visual inspection to detect damage of all spring beam support fittings of the affected strut. Prior to further flight, replace any cracked or damaged parts with new parts.

(iii) Repeat the inspection of the surfaces of the spring beam required by paragraph (a) of this AD thereafter at intervals not to exceed 300 flight cycles.

(b) Accomplishment of all of the following actions in accordance with Boeing Overhaul Manual, Section 54–00–01, constitutes terminating action for the requirements of this AD.

(1) Remove the spring beam.

(2) Accomplish a fluorescent dye penetrant inspection.

(3) Zero-time overhaul the spring beam.

(4) Reinstall that spring beam.

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(e) The inspections and replacement shall be done in accordance with Boeing Alert Service Bulletin 747–54A2171, dated October 31, 1994. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(f) This amendment becomes effective on December 22, 1994.

Issued in Renton, Washington, on November 30, 1994.

James V. Devany, Acting Manager,

Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 94–29919 Filed 12–6–94; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 864, 866, 868, 870, 872, 874, 876, 878, 880, 882, 886, 888, 890, and 892

[Docket No. 94M–0260]

Medical Devices; Exemptions From Premarket Notification for Certain Classified Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is exempting 148 generic types of class I devices from the requirement of premarket notification, with limitations. For the exempted devices, FDA has determined that manufacturers' submissions of premarket notifications are unnecessary for the protection of the public health and that the agency's review of such submissions will not advance its public health mission. The exemptions allow

the agency to make better use of its resources and thus better serve the public.

DATES: Effective January 6, 1995. Beginning on January 6, 1995, all device manufacturers who have 510(k) submissions pending FDA review for devices falling within a generic category which is subject to this rule, will receive a letter stating that the device is exempt from the premarket notification requirements of the act.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ–84), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4765 ext. 157.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 21, 1994 (59 FR 37378), FDA issued a proposed rule to exempt 164 generic types of class I devices from the requirement of premarket notification, with limitations. Interested persons were given until October 19, 1994 to comment on the proposed rule.

II. Comments

During the comment period, FDA received comments requesting that various devices be added to the list of devices that the agency was proposing be exempt from the requirement of premarket notification. The agency also received comments requesting that existing exemptions from the requirement of premarket notification for several devices, when made of certain materials, be expanded to include all devices within the classification, regardless of material composition. FDA is considering these comments and will address them in a future issue of the **Federal Register**.

Several comments requested that certain devices proposed for exemption from premarket notification also be exempted from the requirements of current good manufacturing practices (CGMP's) and records and reports. FDA has decided not to grant these additional exemptions at this time. Pursuant to 21 CFR 820.1(d), any person petitioning for an exemption from any device CGMP requirement is required to follow the procedures set forth in 21 CFR 10.30. Accordingly, the devices listed in this final rule as exempt from premarket notification continue to be subject to applicable CGMP requirements. FDA believes that compliance with CGMP's is necessary in order to ensure adequate protection of the public health

III. Conclusion

Several comments questioned the appropriateness of the proposed exemptions for a small number of the devices. In addition, FDA is reconsidering the appropriateness or scope of the proposed exemptions for several devices included in the proposed rule. Therefore, FDA is deferring action on the following 16 devices in order to review these comments and to reevaluate whether certain of the devices should be exempted from the requirement of premarket notification.

TABLE 1

CFR section	Device
862.2270 ..	Thin-layer chromatography system for clinical use.
862.2310 ..	Clinical sample concentrator.
862.2320 ..	Beta or gamma counter for clinical use.
862.2485 ..	Electrophoresis apparatus for clinical use.
862.2720 ..	Plasma oncometer for clinical use.
862.2800 ..	Refractometer for clinical use.
862.2920 ..	Plasma viscometer for clinical use.
864.2280 ..	Cultured animal and human cells.
866.5570 ..	Lactoferrin immunological test system.
868.5620 ..	Breathing mouthpiece.
868.5675 ..	Rebreathing device.
868.5700 ..	Nonpowered oxygen tent.
872.3740 ..	Retentive and splinting pin.
872.3810 ..	Root canal post.
872.6100 ..	Anesthetic warmer.
886.5850 ..	Sunglasses (nonprescription).

FDA will address these devices in a future issue of the **Federal Register.**

FDA received no adverse comments on 148 of the devices that it proposed be exempted from the requirement of premarket notification. For these 148 devices, FDA has concluded that manufacturers' submissions of premarket notifications are unnecessary for the protection of the public health and that the agency's review of such submissions will not advance its public health mission. Thus, FDA is finalizing the exemptions for these 148 devices from premarket notification procedures.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(2) 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.

V. Analysis of Impacts

FDA has examined the impacts of the final 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 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 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 this final rule reduces a regulatory burden by exempting manufacturers of devices subject to the final rule from the requirements of premarket notification, the agency 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.

List of Subjects

21 CFR Part 864

Blood, Medical devices, Packaging and containers.

21 CFR Parts 868, 870, 872, 874, 876, 878, 880, 882, 888, and 890

Medical devices.

21 CFR Part 866

Biologics, Laboratories, Medical devices.

21 CFR Part 886

Medical devices, Ophthalmic goods and services.

21 CFR Part 892

Medical devices, Radiation protection, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 864, 866, 868, 870, 872, 874, 876, 878, 880, 882, 886, 888, 890, and 892 are amended as follows:

PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

1. The authority citation for 21 CFR part 864 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 864.5350 is amended by revising paragraph (b) to read as follows:

§ 864.5350 Microsedimentation centrifuge.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

3. Section 864.7660 is amended by revising paragraph (b) to read as follows:

§ 864.7660 Leukocyte alkaline phosphatase test.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

4. Section 864.7675 is amended by revising paragraph (b) to read as follows:

§ 864.7675 Leukocyte peroxidase test.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

5. Section 864.7900 is amended by revising paragraph (b) to read as follows:

§ 864.7900 Thromboplastin generation test.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

6. Section 864.8500 is amended by revising paragraph (b) to read as follows:

§ 864.8500 Lymphocyte separation medium.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

7. The authority citation for 21 CFR part 866 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).

8. Section 866.5170 is amended by revising paragraph (b) to read as follows:

§ 866.5170 Breast milk immunological test system.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

9. Section 866.5220 is amended by revising paragraph (b) to read as follows:

§ 866.5220 Cohn fraction II immunological test system.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

10. Section 866.5230 is amended by revising paragraph (b) to read as follows:

§ 866.5230 Colostrum immunological test system.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

11. Section 866.5360 is amended by revising paragraph (b) to read as follows:

§ 866.5360 Cohn fraction IV immunological test system.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

12. Section 866.5370 is amended by revising paragraph (b) to read as follows:

§ 866.5370 Cohn fraction V immunological test system.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

13. Section 866.5540 is amended by revising paragraph (b) to read as follows:

§ 866.5540 Immunoglobulin G (Fd fragment specific) immunological test system.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

14. Section 866.5700 is amended by revising paragraph (b) to read as follows:

§ 866.5700 Whole human plasma or serum immunological test system.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 868—ANESTHESIOLOGY DEVICES

15. The authority citation for 21 CFR part 868 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).

16. Section 868.5340 is amended by revising paragraph (b) to read as follows:

§ 868.5340 Nasal oxygen cannula.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

17. Section 868.5350 is amended by revising paragraph (b) to read as follows:

§ 868.5350 Nasal oxygen catheter.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 870—CARDIOVASCULAR DEVICES

18. The authority citation for 21 CFR part 870 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).

19. Section 870.1875 is amended by revising paragraph (a)(2) to read as follows:

§ 870.1875 Stethoscope.

(a) * * *

(2) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

* * * * *

PART 872—DENTAL DEVICES

20. The authority citation for 21 CFR part 872 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).

21. Section 872.1500 is amended by revising paragraph (b) to read as follows:

§ 872.1500 Gingival fluid measurer.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

22. Section 872.1820 is amended by revising paragraph (b) to read as follows:

§ 872.1820 Dental X-ray exposure alignment device.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

23. Section 872.3100 is amended by revising paragraph (b) to read as follows:

§ 872.3100 Dental amalgamator.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

24. Section 872.3130 is amended by revising paragraph (b) to read as follows:

§ 872.3130 Preformed anchor.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

25. Section 872.3165 is amended by revising paragraph (b) to read as follows:

§ 872.3165 Precision attachment.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

26. Section 872.3240 is amended by revising paragraph (b) to read as follows:

§ 872.3240 Dental bur.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

27. Section 872.3285 is amended by revising paragraph (b) to read as follows:

§ 872.3285 Preformed clasp.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

28. Section 872.3330 is amended by revising paragraph (b) to read as follows:

§ 872.3330 Preformed crown.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

29. Section 872.3350 is amended by revising paragraph (b) to read as follows:

§ 872.3350 Gold or stainless steel cusp.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

30. Section 872.3360 is amended by revising paragraph (b) to read as follows:

§ 872.3360 Preformed cusp.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

31. Section 872.3410 is amended by revising paragraph (b) to read as follows:

§ 872.3410 Ethylene oxide homopolymer and/or carboxymethylcellulose sodium denture adhesive.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

32. Section 872.3450 is amended by revising paragraph (b) to read as follows:

§ 872.3450 Ethylene oxide homopolymer and/or karaya denture adhesive.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

33. Section 872.3490 is amended by revising paragraph (b) to read as follows:

§ 872.3490 Carboxymethylcellulose sodium and/or polyvinylmethylether maleic acid calcium-sodium double salt denture adhesive.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

34. Section 872.3520 is amended by revising paragraph (b) to read as follows:

§ 872.3520 OTC denture cleanser.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

35. Section 872.3530 is amended by revising paragraph (b) to read as follows:

§ 872.3530 Mechanical denture cleaner.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

36. Section 872.3580 is amended by revising paragraph (b) to read as follows:

§ 872.3580 Preformed gold denture tooth.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

37. Section 872.3670 is amended by revising paragraph (b) to read as follows:

§ 872.3670 Resin impression tray material.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

38. Section 872.3900 is amended by revising paragraph (b) to read as follows:

§ 872.3900 Posterior artificial tooth with a metal insert.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

39. Section 872.3910 is amended by revising paragraph (b) to read as follows:

§ 872.3910 Backing and facing for an artificial tooth.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

40. Section 872.4130 is amended by revising paragraph (b) to read as follows:

§ 872.4130 Intraoral dental drill.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

41. Section 872.4535 is amended by revising paragraph (b) to read as follows:

§ 872.4535 Dental diamond instrument.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

42. Section 872.4620 is amended by revising paragraph (b) to read as follows:

§ 872.4620 Fiber optic dental light.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

43. Section 872.4730 is amended by revising paragraph (b) to read as follows:

§ 872.4730 Dental injecting needle.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

44. Section 872.5410 is amended by revising paragraph (b) to read as follows:

§ 872.5410 Orthodontic appliance and accessories.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

45. Section 872.5525 is amended by revising paragraph (b) to read as follows:

§ 872.5525 Preformed tooth positioner.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

46. Section 872.5550 is amended by revising paragraph (b)(1) to read as follows:

§ 872.5550 Teething ring.

* * * * *

(b)(1) *Classification.* Class I if the teething ring does not contain a fluid, such as water. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

* * * * *

47. Section 872.6030 is amended by revising paragraph (b) to read as follows:

§ 872.6030 Oral cavity abrasive polishing agent.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

48. Section 872.6140 is amended by revising paragraph (b) to read as follows:

§ 872.6140 Articulation paper.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

49. Section 872.6250 is amended by revising paragraph (b) to read as follows:

§ 872.6250 Dental chair and accessories.

* * * * *

(b) *Classification.* Class I. The dental chair without the operative unit device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

50. Section 872.6300 is amended by revising paragraph (b) to read as follows:

§ 872.6300 Rubber dam and accessories.

* * * * *

(b) *Classification.* Class I. The accessories to the device, i.e., rubber dam clamp, rubber dam frame and forceps for a rubber dam clamp, are exempt from the premarket notification procedures in subpart E of part 807 of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

51. Section 872.6475 is amended by revising paragraph (b) to read as follows:

§ 872.6475 Heat source for bleaching teeth.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

52. Section 872.6510 is amended by revising paragraph (b) to read as follows:

§ 872.6510 Oral irrigation unit.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

53. Section 872.6640 is amended by revising paragraph (b) to read as follows:

§ 872.6640 Dental operative unit and accessories.

* * * * *

(b) *Classification.* Class I. The accessories tray to the dental operative unit is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

54. Section 872.6865 is amended by revising paragraph (b) to read as follows:

§ 872.6865 Powered toothbrush.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

55. Section 872.6890 is amended by revising paragraph (b) to read as follows:

§ 872.6890 Intraoral dental wax.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

PART 874—EAR, NOSE, AND THROAT DEVICES

56. The authority citation for 21 CFR part 874 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).

57. Section 874.3375 is amended by revising paragraph (b) to read as follows:

§ 874.3375 Battery-powered artificial larynx.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

58. Section 874.4750 is amended by revising paragraph (b) to read as follows:

§ 874.4750 Laryngostroboscope.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

59. Section 874.5220 is amended by revising paragraph (b) to read as follows:

§ 874.5220 Ear, nose, and throat drug administration device.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

60. Section 874.5800 is amended by revising paragraph (b) to read as follows:

§ 874.5800 External nasal splint.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

61. 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).

62. Section 876.5970 is amended by revising paragraph (b) to read as follows:

§ 876.5970 Hernia support.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The device is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

63. The authority citation for 21 CFR part 878 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 522, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371).

64. Section 878.1800 is amended by revising paragraph (b) to read as follows:

§ 878.1800 Speculum and accessories.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

65. Section 878.3750 is amended by revising paragraph (b) to read as follows:

§ 878.3750 External prosthesis adhesive.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

66. Section 878.3800 is amended by revising paragraph (b) to read as follows:

§ 878.3800 External aesthetic restoration prosthesis.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. If the device is intended for use without an external prosthesis adhesive to fasten it to the body, the device is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

67. Section 878.3900 is amended by revising paragraph (b) to read as follows:

§ 878.3900 Inflatable extremity splint.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

68. Section 878.4100 is amended by revising paragraph (b) to read as follows:

§ 878.4100 Organ bag.

* * * * *

(b) *Classification.* Class I. The intestinal organ bag device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

69. Section 878.4380 is amended by revising paragraph (b) to read as follows:

§ 878.4380 Drape adhesive.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

70. Section 878.4440 is amended by revising paragraph (b) to read as follows:

§ 878.4440 Eye pad.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

71. Section 878.4470 is amended by revising paragraph (b) to read as follows:

§ 878.4470 Surgeon's gloving cream.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

72. Section 878.4635 is amended by revising paragraph (b) to read as follows:

§ 878.4635 Ultraviolet lamp for tanning.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

73. Section 878.4660 is amended by revising paragraph (b) to read as follows:

§ 878.4660 Skin marker.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

74. Section 878.4700 is amended by revising paragraph (b) to read as follows:

§ 878.4700 Surgical microscope and accessories.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

75. Section 878.4730 is amended by revising paragraph (b) to read as follows

§ 878.4730 Surgical skin degreaser or adhesive tape solvent.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

76. Section 878.4800 is amended by revising paragraph (b) to read as follows:

§ 878.4800 Manual surgical instrument for general use.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

77. Section 878.4930 is amended by revising paragraph (b) to read as follows

§ 878.4930 Suture retention device.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

78. Section 878.4950 is amended by revising paragraph (b) to read as follows:

§ 878.4950 Manual operating table and accessories and manual operating chair and accessories.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

79. Section 878.5900 is amended by revising paragraph (b) to read as follows:

§ 878.5900 Nonpneumatic tourniquet.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

80. The authority citation for 21 CFR part 880 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).

81. Section 880.2400 is amended by revising paragraph (b) to read as follows:

§ 880.2400 Bed-patient monitor.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

82. Section 880.2720 is amended by revising paragraph (b)(1) to read as follows:

§ 880.2720 Patient scale.

* * * * *

(b) *Classification.* (1) Class I for a mechanical or battery powered patient scale. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

* * * * *

83. Section 880.5180 is amended by revising paragraph (b) to read as follows:

§ 880.5180 Burn sheet.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

84. Section 880.5210 is amended by revising paragraph (b) to read as follows:

§ 880.5210 Intravascular catheter securement device.

* * * * *

(b) *Classification.* Classs I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

85. Section 880.5240 is amended by revising paragraph (b) to read as follows:

§ 880.5240 Medical adhesive tape and adhesive bandage.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

86. Section 880.5630 is amended by revising paragraph (b) to read as follows:

§ 880.5630 Nipple shield.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

87. Section 880.5740 is amended by revising paragraph (b) to read as follows:

§ 880.5740 Suction snakebite kit.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

88. Section 880.5780 is amended by revising paragraph (b)(2) to read as follows:

§ 880.5780 Medical support stocking.

* * * * *

(b) * * *

(2) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The device is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

89. Section 880.5950 is amended by revising paragraph (b) to read as follows:

§ 880.5950 Umbilical occlusion device.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

90. Section 880.6060 is amended by revising paragraph (b) to read as follows:

§ 880.6060 Medical disposable bedding.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

91. Section 880.6150 is amended by revising paragraph (b) to read as follows:

§ 880.6150 Ultrasonic cleaner for medical instruments.

* * * * *

(b) *Classification.* Class I. The device, including any solutions intended for use with the device for cleaning and sanitizing the instruments, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

92. Section 880.6190 is amended by revising paragraph (b) to read as follows:

§ 880.6190 Mattress cover for medical purposes.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

93. Section 880.6900 is amended by revising paragraph (b) to read as follows:

§ 880.6900 Hand-carried stretcher.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The device is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

PART 882—NEUROLOGICAL DEVICES

94. The authority citation for 21 CFR part 882 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).

95. Section 882.1430 is amended by revising paragraph (b) to read as follows:

§ 882.1430 Electroencephalograph test signal generator.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

96. Section 882.1700 is amended by revising paragraph (b) to read as follows:

§ 882.1700 Percussor.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

97. Section 882.1925 is amended by revising paragraph (b) to read as follows:

§ 882.1925 Ultrasonic scanner calibration test block.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

98. Section 882.4030 is amended by revising paragraph (b) to read as follows:

§ 882.4030 Skull plate anvil.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

99. Section 882.4125 is amended by revising paragraph (b) to read as follows:

§ 882.4125 Neurosurgical chair.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

100. Section 882.4190 is amended by revising paragraph (b) to read as follows:

§ 882.4190 Clip forming/cutting instrument.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

101. Section 882.4200 is amended by revising paragraph (b) to read as follows:

§ 882.4200 Clip removal instrument.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

102. Section 882.4215 is amended by revising paragraph (b) to read as follows:

§ 882.4215 Clip rack.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

103. Section 882.4440 is amended by revising paragraph (b) to read as follows:

§ 882.4440 Neurosurgical headrest.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

104. Section 882.4500 is amended by revising paragraph (b) to read as follows:

§ 882.4500 Cranioplasty material forming instrument.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

105. Section 882.4525 is amended by revising paragraph (b) to read as follows:

§ 882.4525 Microsurgical instrument.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

106. Section 882.4535 is amended by revising paragraph (b) to read as follows:

§ 882.4535 Nonpowered neurosurgical instrument.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

107. Section 882.4600 is amended by revising paragraph (b) to read as follows:

§ 882.4600 Leukotome.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

108. Section 882.4900 is amended by revising paragraph (b) to read as follows:

§ 882.4900 Skullplate screwdriver.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 886—OPHTHALMIC DEVICES

109. The authority citation for 21 CFR part 886 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).

110. Section 886.1040 is amended by revising paragraph (b) to read as follows:

§ 886.1040 Ocular esthesiometer.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

111. Section 886.1050 is amended by revising paragraph (b) to read as follows:

§ 886.1050 Adaptometer (biophotometer).

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

112. Section 886.1070 is amended by revising paragraph (b) to read as follows:

§ 886.1070 Anomaloscope.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

113. Section 886.1090 is amended by revising paragraph (b) to read as follows:

§ 886.1090 Haidlinger brush.

* * * * *

(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

114. Section 886.1140 is amended by revising paragraph (b) to read as follows:

§ 886.1140 Ophthalmic chair.

* * * * *

(b) *Classification.* Class I. The AC-powered device and the manual device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The manual device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

115. Section 886.1160 is amended by revising paragraph (b) to read as follows:

§ 886.1160 Color vision plate illuminator.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

116. Section 886.1250 is amended by revising paragraph (b) to read as follows:

§ 886.1250 Euthyscope.

* * * * *

(b) *Classification.* Class I for the battery powered device. The battery powered device is exempt from premarket notification procedures in subpart E of part 807 of this chapter. Class II for the AC-powered device.

117. Section 886.1290 is amended by revising paragraph (b) to read as follows:

§ 886.1290 Fixation device.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

118. Section 886.1340 is amended by revising paragraph (b) to read as follows:

§ 886.1340 Haploscope.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

119. Section 886.1350 is amended by revising paragraph (b) to read as follows:

§ 886.1350 Keratoscope.

* * * * *

(b) *Classification.* Class I. The AC-powered device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter only when the device does not include computer software in the unit. The battery-powered device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The battery-powered device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning

records, and § 820.198, with respect to complaint files.

120. Section 886.1425 is amended by revising paragraph (b) to read as follows:

§ 886.1425 Lens measuring instrument.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

121. Section 886.1430 is amended by revising paragraph (b) to read as follows:

§ 886.1430 Ophthalmic contact lens radius measuring device.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

122. Section 886.1435 is amended by revising paragraph (b) to read as follows:

§ 886.1435 Maxwell spot.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

123. Section 886.1450 is amended by revising paragraph (b) to read as follows:

§ 886.1450 Corneal radius measuring device.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter only when the device does not include computer software in the unit or topographers.

124. Section 886.1660 is amended by revising paragraph (b) to read as follows:

§ 886.1660 Gonioscopic prism.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

125. Section 886.1680 is amended by revising paragraph (b) to read as follows:

§ 886.1680 Ophthalmic projector.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

126. Section 886.1690 is amended by revising paragraph (b) to read as follows:

§ 886.1690 Pupillograph.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

127. Section 886.1700 is amended by revising paragraph (b) to read as follows:

§ 886.1700 Pupillometer.

* * * * *

(b) *Classification.* Class I. The AC-powered device and the manual device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The manual device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

128. Section 886.1810 is amended by revising paragraph (b) to read as follows:

§ 886.1810 Tangent screen (campimeter).

* * * * *

(b) *Classification.* Class I. The AC-powered device and the battery-powered device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The battery-powered device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

129. Section 886.1860 is amended by revising paragraph (b) to read as follows:

§ 886.1860 Ophthalmic instrument stand.

* * * * *

(b) *Classification.* Class I. The AC-powered device and the battery-powered device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The battery-powered device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

130. Section 886.1870 is amended by revising paragraph (b) to read as follows:

§ 886.1870 Stereoscope.

* * * * *

(b) *Classification.* Class I. The AC-powered device and the battery-powered device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The battery-powered device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

131. Section 886.1910 is amended by revising paragraph (b) to read as follows:

§ 886.1910 Spectacle dissociation test system.

* * * * *

(b) *Classification.* Class I. The AC-powered device and the battery-powered device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The battery-powered device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

132. Section 886.1945 is amended by revising paragraph (b) to read as follows

§ 886.1945 Transilluminator.

* * * * *

(b) *Classification.* Class I for the battery-powered device. Class II for the AC-powered device. The battery-powered Class I device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

133. Section 886.4250 is amended by revising paragraph (b) to read as follows:

§ 886.4250 Ophthalmic electrolysis unit.

* * * * *

(b) *Classification.* Class I for the battery-powered device. Class II for the AC-powered device. The battery-powered Class I device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

134. Section 886.4350 is amended by revising paragraph (b) to read as follows:

§ 886.4350 Manual ophthalmic surgical instrument.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter only when the device meets the ANSI standard on optic radiation limits.

135. Section 886.4360 is amended by revising paragraph (b) to read as follows:

§ 886.4360 Ocular surgery irrigation device.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

136. Section 886.4570 is amended by revising paragraph (b) to read as follows:

§ 886.4570 Ophthalmic surgical marker.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket

notification procedures in subpart E of part 807 of this chapter.

137. Section 886.4750 is amended by revising paragraph (b) to read as follows:

§ 886.4750 Ophthalmic eye shield.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The device also is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

138. Section 886.4855 is amended by revising paragraph (b) to read as follows:

§ 886.4855 Ophthalmic instrument table.

* * * * *

(b) *Classification.* Class I. The AC-powered device and the manual device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The manual device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

139. Section 886.5820 is amended by revising paragraph (b) to read as follows:

§ 886.5820 Closed-circuit television reading system.

* * * * *

(b) *Classification.* Class I. The AC-powered device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

140. Section 886.5840 is amended by revising paragraph (b) to read as follows:

§ 886.5840 Magnifying spectacles.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

141. Section 886.5842 is amended by revising paragraph (b) to read as follows:

§ 886.5842 Spectacle frame.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

142. Section 886.5844 is amended by revising paragraph (b) to read as follows:

§ 886.5844 Prescription spectacle lens.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

143. Section 886.5900 is amended by revising paragraph (b) to read as follows:

§ 886.5900 Electronic vision aid.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

144. Section 886.5915 is amended by revising paragraph (b) to read as follows:

§ 886.5915 Optical vision aid.

* * * * *

(b) *Classification.* Class I. The AC-powered device and the battery-powered device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The battery-powered device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

PART 888—ORTHOPEDIC DEVICES

145. The authority citation for 21 CFR part 888 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).

146. Section 888.4200 is amended by revising paragraph (b) to read as follows:

§ 888.4200 Cement dispenser.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

147. Section 888.4210 is amended by revising paragraph (b) to read as follows:

§ 888.4210 Cement mixer for clinical use.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

148. Section 888.4230 is amended by revising paragraph (b) to read as follows:

§ 888.4230 Cement ventilation tube.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

149. Section 888.4540 is amended by revising paragraph (b) to read as follows:

§ 888.4540 Orthopedic manual surgical instrument.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

150. Section 888.5940 is amended by revising paragraph (b) to read as follows:

§ 888.5940 Cast component.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

PART 890—PHYSICAL MEDICINE DEVICES

151. The authority citation for 21 CFR part 890 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).

152. Section 890.1175 is amended by revising paragraph (b) to read as follows:

§ 890.1175 Electrode cable.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The devices are also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

153. Section 890.3100 is amended by revising paragraph (b) to read as follows:

§ 890.3100 Mechanical chair.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

154. Section 890.3750 is amended by revising paragraph (b) to read as follows:

§ 890.3750 Mechanical table.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

155. Section 890.3920 is amended by revising paragraph (b) to read as follows:

§ 890.3920 Wheelchair component.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

156. Section 890.3940 is amended by revising paragraph (b) to read as follows:

§ 890.3940 Wheelchair platform scale.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

157. Section 890.5765 is amended by revising paragraph (b) to read as follows:

§ 890.5765 Pressure-applying device.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 892—RADIOLOGY DEVICES

158. The authority citation for 21 CFR part 892 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).

159. Section 892.1130 is amended by revising paragraph (b) to read as follows:

§ 892.1130 Nuclear whole body counter.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

160. Section 892.1350 is amended by revising paragraph (b) to read as follows:

§ 892.1350 Nuclear scanning bed.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter only when the device is labeled with weight limit, is used with planar scanning only, and is not for diagnostic X-ray use.

161. Section 892.1640 is amended by revising paragraph (b) to read as follows:

§ 892.1640 Radiographic film marking system.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

162. Section 892.5740 is amended by revising paragraph (b) to read as follows:

§ 892.5740 Radionuclide teletherapy source.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

Dated: November 30, 1994.

William K. Hubbard,

Interim Deputy Commissioner for Policy.

[FR Doc. 94–30025 Filed 12–2–94; 12:01 pm]

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DEPARTMENT OF JUSTICE

Office of Justice Programs

28 CFR Part 91

[OJP No. 1011]

RIN 1121–AA25

Violent Offender Incarceration and Truth in Sentencing Incentive Grant Program

AGENCY: Department of Justice, Office of Justice Programs (OJP).

ACTION: Interim final rule.

SUMMARY: This interim rule implements and requests comments regarding the Violent Offender Incarceration and Truth in Sentencing Incentive Grant Program, Subtitle A of Title II of the Violent Crime Control and Law Enforcement Act of 1994.

The Violent Offender Incarceration and Truth in Sentencing Grant Program will provide grants to states, and states organized in multi-state compacts, for assistance to correctional systems. These regulations are being issued in accordance with the mandate in Subtitle A of Title II that rules and regulations regarding the uses of grant funds under this program be issued. While this rule discusses the implementation of the overall Subtitle A program, fiscal year 1995 funds have only been appropriated for the construction-related costs of correctional boot camps.

DATES: Interim rule effective on December 7, 1994; comments must be received March 7, 1995.

ADDRESSES: Comments may be sent to Marlene Beckman at the Office of Justice Programs, 633 Indiana Avenue, 13th Floor, NW, Washington, DC 20531.

FOR FURTHER INFORMATION CONTACT: The Department of Justice Response Center at 1–800–421–6770 or (202) 307–1480.

SUPPLEMENTARY INFORMATION: Federal funding is authorized under Subtitle A of Title II of the Violent Crime Control and Law Enforcement Act of 1994 (Subtitle A), Public Law 103–322, for grants to states, and states organized in multi-state compacts, for assistance to adult and juvenile correctional systems. The program recognizes that states and local jurisdictions have experienced substantial increases in jail, prison and juvenile confinement populations in recent years, resulting in escalating costs and serious difficulties in managing overcapacity correctional populations. Because of these constraints, correctional systems have often been unable to implement new programs, develop alternative confinement strategies, or open new facilities. This program seeks to provide funds to address the immediate needs of correctional facilities and programs.

In particular, the program emphasizes the need to make available both conventional jail and prison space for the confinement of violent offenders and to ensure that violent offenders remain incarcerated for substantial periods of time through the implementation of truth in sentencing laws. Accordingly, Subtitle A directs the Attorney General to award grants to construct, develop, expand, modify, operate, or improve correctional facilities, including boot camp facilities and other alternative correctional facilities that will free secure prison space for the confinement of violent offenders.

Fifty percent of the total amount of funds appropriated each year will be allocated for Truth in Sentencing Incentive Grants and the other 50 percent will be allocated for Violent Offender Incarceration Grants, 85 percent of which is to be distributed by specified formula with the remaining 15 percent available for discretionary grant awards.

The formula amount available to carry out the grant programs for any fiscal year will be allocated to each eligible state based on Part 1 violent crime data reported to the Federal Bureau of Investigation for use in the Uniform Crime Reports (UCR). If such data is unavailable, applicants may also utilize figures as reported in publications by the Bureau of Justice Statistics (BJS). (See, e.g., "Census of State and Local Correctional Facilities, 1990.")

The statute contemplates the availability of $7.9 billion in funding over six years, beginning with $175 million authorized in fiscal year 1995. It is important to note, however, that Congress appropriated only $24.5 million for Subtitle A programs for fiscal year 1995. Moreover, the Appropriations Act limits these funds to

a discretionary grant program for the construction of correctional boot camps. Specifically, grant awards in fiscal year 1995 are to develop, construct, or expand boot camp programs which include coordinated, intensive aftercare services following release. It is anticipated that program guidelines and information outlining the application process for adult and juvenile boot camp fiscal year 1995 grant awards will be available in January 1995.

Statement of the Problem

State and local prison populations continue to grow. Moreover, there are a number of states and local jurisdictions under court order because of overcrowding in their correctional facilities. The majority of jurisdictions operate above the total rated capacity for their correctional facilities. Those facilities under court order for overcrowding which have taken steps to control their burgeoning inmate populations tend to operate at or near capacity in order to remain in compliance with the court orders.

Correctional systems faced with rising prison populations and court-ordered ceilings have responded in various ways. Some have implemented population management task forces to ensure that violent criminals are not released as a result of accommodating nonviolent offenders. Others have simply released offenders when their institutions reach a certain population level, without significant controls over the security classifications of the inmates. Still other systems under court order have implemented statutory release programs.

The Violent Crime Control and Law Enforcement Act of 1994

Subtitle A provides for immediate assistance to correctional systems to contend with this growing inmate population crisis. Of primary importance is the recognition that there must be adequate conventional confinement space for violent offenders, both adults and juveniles, to serve a substantial portion of their sentences. This program, therefore, provides grants to assist correctional systems in managing a comprehensive approach which will provide for the confinement of violent offenders; help address the problems associated with overcapacity in correctional facilities through the improvement, development, expansion or modification of present facilities and programs; and support comprehensive programs and treatment that will assist in reducing recidivism.

Federal, State and Local Partnerships

Because crime is primarily a state and local issue, the Subtitle A grant program envisions a federal, state, and local collaboration to address the problems associated with the incarceration and punishment of violent offenders. State and local government officials were involved in the congressional hearings that guided this legislation, and will continue to be involved as the Department of Justice moves forward in establishing policy guidance, developing regulations, and implementing program guidelines.

In addition, this grant program provides flexibility to states and local governments in utilizing federal funds to plan, construct, and operate correctional facilities in ways that best meet their needs and in the most cost-effective manner. Built into the program is the recognition that correctional systems can use grant funds in a variety of ways to ensure the greatest and most timely impact.

Under Subtitle A, corrections systems will have the ability to quickly bring on-line additional bed space in facilities which, although construction has been completed, are not being utilized due to funding constraints. States and local agencies can also activate prison and jail expansion and juvenile corrections projects that have been planned, but not launched, due to lack of funds. The grant program further provides for the expansion of alternative correctional options for nonviolent offenders which will free secure bed space for dangerous offenders to serve their sentences.

Moreover, corrections systems will have flexibility in using surplus federal property. Beds for violent offenders can be made available in secure facilities through the conversion of closed military facilities or other appropriate federal facilities to facilities for housing low-security inmates.

Subtitle A also recognizes the benefits of regional prisons, particularly for adjoining localities. The economies of scale resulting from a multi-state compact prison are particularly beneficial for confining specialized groups of offenders, such as medical/psychiatric inmates, inmates requiring protective custody, and high security inmates.

The grant program balances appropriate accountability through various eligibility criteria, the availability of technical assistance, and the evaluation of programs implemented with these funds, with the flexibility states and local governments require and deserve based on their individual needs and expertise. Grant eligibility criteria specifically provide for the involvement of counties and local governments and the sharing of funds with these entities.

Moreover, the federal role provides sufficient structure and definition in the eligibility criteria to meet the program's goals, while allowing for judgment by grant recipients to take into account the states' various unique situations, criminal and juvenile justice practices, and correctional systems. The program accounts for the different needs of the states and local entities, and reflects that there is no "national standard" approach that will suit all jurisdictions. The grant monies are available for the range of correctional needs such as system planning and facility development, as well as the construction, expansion, modification, improvement, and operation of a variety of correctional facilities.

Violent Juvenile Crime

Concern also continues nationwide over the escalation in violent juvenile crime. According to the FBI's Uniform Crime Reports, juvenile arrests for violent offenses increased dramatically over the five-year period from 1988 to 1992—47 percent—while adult violent crime arrests increased 19 percent. The estimated 129,600 Violent Crime Index arrests of juveniles in 1992 was the highest in our history, with 3,300 arrests for murder, 6,300 for forcible rape, 45,700 for robbery and 74,400 for aggravated assault. Moreover, during the past few years, there has been a marked escalation of homicides by juvenile offenders. Teenage homicides have more than doubled since 1984, and juvenile homicides involving firearms have increased 175 percent since 1983. Of particular importance is that the size of the current 14–17 year-old population, which has been responsible for much of the recent youth violence, will increase by about 20 percent in the next decade.

The "Comprehensive Strategy for Serious, Violent and Chronic Juvenile Offenders," developed by the Department's Office of Juvenile Justice and Delinquency Prevention, is the centerpiece of the Department's response to growing juvenile crime. The Subtitle A grant program is an integral part of the comprehensive strategy's intervention component. The program is based on the recognition that an effective model for the treatment and rehabilitation of delinquent offenders must combine accountability and sanctions with increasingly intensive treatment and rehabilitative efforts at every stage of the continuum.

The intervention component calls for establishing a range of graduated sanctions that includes both immediate interventions and intermediate sanctions, including both nonresidential and residential placements and programming. Boot camps offer an intermediate sanction for nonviolent juvenile offenders. These programs should be short-term and include a formal aftercare phase, actively involving the family and the community in supporting and reintegrating the juvenile into the community.

While the strategy encourages the use of non-residential community-based programs and intensive supervision programs for many juvenile offenders, it recognizes that the criminal behavior of some serious, violent and chronic offenders requires the use of secure detention and corrections facilities to protect the community and provide a structured treatment environment. This grant program will facilitate jurisdictions in meeting the challenge of placing juvenile offenders in need of confinement in secure facilities.

Grants for Correctional Facilities

The Subtitle A authorization provides for two different grant programs: (1) Violent Offender Incarceration Grants, and (2) Truth in Sentencing Incentive Grants. Of the total federal funding authorized to Subtitle A grant programs each year, 50 percent is allocated for each of these two grant initiatives. With the exception of a limited discretionary grant program, this funding will be distributed to states based on the formula specified in Subtitle A. Although the statute provides for states and multi-state compacts as the only eligible grant recipients, Subtitle A requires that states involve counties and other units of local government and share funds received under this program with them.

To be eligible to receive funding under either of the Subtitle A programs, states must comply with a series of assurances involving sentencing policies and practices and other guarantees of sound correctional systems to ensure that violent offenders are sufficiently incapacitated and that the public is protected.

Included in the assurances are requirements that the state: (1) Implement sentencing reforms that ensure violent offenders receive sufficiently severe punishments, (2) recognize the rights and needs of crime victims, and (3) develop a comprehensive correctional management plan that includes diversion programs, particularly drug diversion programs, community corrections programs, systems designed to accurately evaluate and classify inmates within the system, and programs and treatment designed to assist in reducing recidivism, including rehabilitation and treatment programs and job skills. Emphasis will be placed on a corrections system's ability to plan for and implement these basic components of a comprehensive and coordinated approach to correctional policy.

Comprehensive Correctional Planning

By definition, a comprehensive system involves state and local governments; thus, the development of a comprehensive plan necessitates a partnership and collaboration among state and local entities. Because the flow of offenders begins at the local level, both local and state governments play key roles in the punishment of offenders through alternative sanctions and incarceration in correctional facilities. The input of county and municipal juvenile and criminal justice officials will be considered essential to creating an effective overall state strategy to meet the goals of this grant program. Both local and state governments also have a strong interest in any change in the capacity of any component of the corrections system. The statutory assurances are clear in their intent that states are expected to share funds with local units of government in support of effective implementation of the comprehensive plan.

Participants in the comprehensive plan development should represent a broad mix of interested and involved organizations and officials from varying perspectives. Every effort should be made by the state to include mayors, city and county officials, police departments, sheriffs, judges, prosecutors, community corrections administrators, representatives from the treatment and education communities and indigent defense, concerned citizens, and victims' advocates, as well as the juvenile justice system. Applicants should also take an active role in involving state and juvenile justice administrative agencies and advisory boards. The manner in which criminal and juvenile justice functions are structured in various states and their relationships with other justice agencies will affect the roles played in the development of an effective correctional plan.

The comprehensive correctional plan must address how the state has involved local jurisdictions and the plan for sharing funds with local facilities, truth in sentencing and victims' rights issues, and the continuum of correctional options required for adult and juvenile offenders. It must meet the overall goal of incarcerating violent offenders, and must convey the options for nonviolent offenders that will free up traditional bed space to accomplish that goal.

Victims' Rights and Needs

To be eligible to receive grants, states must provide assurances that they have implemented policies that provide for the recognition of the rights and needs of crime victims. No specific requirements for complying with this condition are prescribed by this interim rule in relation to fiscal year 1995 funding because of the need for comprehensive review of the status of victims' rights measures in state systems. State applications for fiscal year 1995 funding should include information on measures which are in effect or under consideration in the state to protect the rights and interests of crime victims.

More definitive guidance will be provided concerning compliance with this condition in a final rule or related guidelines for funding in fiscal year 1996 and thereafter. Areas that have been identified as implicating important rights and needs of crime victims include: (1) Providing notice to victims concerning case and offender status, (2) providing an opportunity for victims to be present at public court proceedings, (3) providing victims the opportunity to be heard at sentencing and parole hearings, (4) providing for restitution and other compensation to victims, and (5) establishing administrative mechanisms or other mechanisms to effectuate these rights.

States that expect to seek funding under this program in fiscal year 1996 or thereafter are encouraged to review the status of victim rights measures in their systems, particularly with reference to the five areas identified above. Federal law incorporates significant measures in each of these areas for federal cases. The provisions of federal law governing these issues may be useful for states as a possible model for reform, if they have not already adopted similar measures in their own systems. See 42 U.S.C. 10606(b)(3), (7), 10607(c) (notice concerning case and offender status); 42 U.S.C. 10606(b)(4) (right to be present at public court proceedings); Rule 32 of the Federal Rules of Criminal Procedure, as amended effective December 1, 1994 (right of allocution in sentencing for victims); 18 U.S.C. 3663, 3553(c) (general restitution provisions for federal cases); 42 U.S.C. 10607(a) and (b), 10607(c)(5) (assignment of

responsibility for victim-related functions).

Truth in Sentencing Incentive Grants

To be eligible to receive funding under the Truth in Sentencing Grant Program, in addition to meeting the assurances listed in Subtitle A, states must also meet certain sentencing requirements. In particular, to qualify for this part of the grant program, states must have in effect sentencing laws that either provide for violent offenders to (1) serve not less than 85 percent of their sentences, or (2) meet other requirements that ensure that violent offenders, and especially repeat violent offenders, remain incarcerated for substantially greater percentages of their imposed sentences.

The Office of Justice Programs is aware that the vast majority of states will at present have difficulty in meeting the condition that violent offenders serve at least 85 percent of the sentence imposed. No specific guidance for complying with this assurance is prescribed at this time both because funding for this program is not available in FY '95, and also because of the need for further review of state compliance issues. Moreover, we are particularly interested in comments from the field on compliance issues and on the definition of "violent offender" for purposes of truth in sentencing grant awards.

FY 1995 Correctional Boot Camp Initiative

The availability of funds each year is, of course, limited by the appropriations process. In fiscal year 1995, Congress has allocated $24.5 million to Subtitle A grant programs and has imposed additional limitations on the uses of these grant funds.

Consistent with congressional intent, grant awards in fiscal year 1995 will be for construction-related costs of correctional boot camps and will be allocated through the discretionary grant component of the Violent Offender Incarceration Grant Program. Construction-related costs are broadly interpreted to include costs associated with both the planning and development of the facility. OJP is expressly precluded, however, from funding operating expenses.

Specifically, grant funds can be used to plan, develop, construct, or expand adult and juvenile boot camp programs which must include coordinated, intensive aftercare services for inmates following release. Pursuant to the requirements specified in Subtitle A, boot camps are correctional programs of no longer than six-months incarceration and must: (1) Exclude offenders who have at any time been convicted of a violent felony or similarly adjudicated juveniles, (2) adhere to a regimented schedule, (3) provide for inmate participation in education, job training and substance abuse counseling or treatment, and (4) coordinate intensive aftercare services with the services provided during the period of confinement.

The program emphasis in fiscal year 1995 will be on the construction, renovation and expansion of correctional boot camp facilities that will free conventional prison, jail and juvenile correctional space for the confinement of violent offenders so they can serve a substantial amount of their imposed sentences. To receive funds, correctional systems will have to demonstrate, through a comprehensive correctional plan and prisoner screening and security classification system, that (1) there is a need for additional secure confinement space for violent offenders, and (2) this need will be met through the construction of a boot camp facility that provides housing otherwise unavailable for nonviolent offenders.

With regard to juvenile facilities, priority will be given to juvenile boot camps that are designed to prevent juvenile offenders at risk from becoming violent offenders. This desired outcome will most likely be accomplished if the jurisdiction engages in efforts that maximize the likelihood that juvenile boot camp participants would otherwise be incarcerated in traditional secure facilities (e.g., participation limited to those youths who have been adjudicated delinquents and who have been sentenced to the juvenile state correctional agency). Among this population, juvenile offenders whose escalating patterns of delinquent behavior indicate that an authoritative boot camp intervention is likely to suppress or abate emerging tendencies towards chronic or violent delinquent behavior should be considered prime candidates for boot camp participation.

To be eligible to receive grants for correctional boot camp construction, states must meet the eligibility criteria outlined for the Violent Offender Incarceration Grant Program, including the assurances specified in Section 20101(b) of Subtitle A.

Detailed program guidelines and application material for the fiscal year 1995 correctional boot camp initiative will be available in January 1995.

Technical Assistance and Training/ Evaluation

In keeping with the intent of Congress to assist states in meeting these assurances, the Department proposes to designate up to 10 percent of the funds available in this program to provide technical assistance and training to states that presently do not meet the required general assurances or want to expand and improve on current efforts in these areas. Specifically, the Department will provide training and assistance to states with the comprehensive corrections planning process, the development of truth in sentencing statutes, and in otherwise moving toward compliance with the required conditions. States which meet the general assurances in fiscal year 1995, or are working toward compliance, will be in a better position to receive grant monies under these programs over the next several years.

Further, it is the intent of the Department that selected federal initiatives under the new anti-crime law be evaluated. To accomplish this goal, a portion of the overall funds authorized under this Subtitle will be set aside for purposes of implementing a national evaluation strategy. Recipients of funds must agree to cooperate with federally-sponsored evaluations of their projects and to conduct evaluations as required by the national evaluation strategy. In addition, recipients of program funds will be required to conduct a local assessment and report on program implementation.

Request for Comments

In submitting comments, please be cognizant of the above-described statutory limitations. In administering the Subtitle A, Correctional Facilities Grant Program, OJP seeks to fulfill congressional intent by ensuring that the statutory limitations are applied appropriately to all recipients.

Comments are particularly encouraged with respect to the following definitions and implementation policy issues:

(1) Definition of "Violent Offender" [§ 91.2(a), § 91.4(b)] (This interim rule reserves the issue for now, but the Department will issue a final rule based on comments received, in advance of the implementation of Subtitle A in fiscal year 1996);

(2) Definition of "Serious Drug Offense" [§ 91.4(b)];

(3) How a state can demonstrate compliance with the assurance that it has implemented, or will implement, correctional policies and programs, including "truth in sentencing laws that: (a) "ensure that violent offenders serve a substantial portion of the sentences imposed," (b) "are designed to provide sufficiently severe punishment for violent offenders,

including violent juvenile offenders," and (c) "the prison time served is appropriately related to the determination that the inmate is a violent offender and for a period of time deemed necessary to protect the public." [§ 91.2(i), § 91.3(b)(1)];

(4) How a state can demonstrate compliance with the condition to "provide for the recognition of the rights and needs of crime victims" [§ 91.3(b)(2)];

(5) How a state can demonstrate that, as a result of the funds received under this section, secure space will be made available for the confinement of violent offenders [§ 91.3(b)(3)];

(6) How to ensure that states have met the condition to involve and share funds received with counties and other units of local government [§ 91.3(b)(5)];

(7) How to define the scope of the Comprehensive Correctional Plan [§ 91.3(d)]; and

(8) How a state can demonstrate compliance with the condition for receiving Truth in Sentencing Incentive Grants, i.e., "persons convicted of violent crimes serve not less than 85% of the sentence imposed" [§ 91.4(b)].

In soliciting comments on the above definitions and key policy implementation issues, OJP hopes to forge a productive federal/state/local partnership in addressing the challenge of providing an effective criminal justice system response to the increased numbers of violent offenders.

The final rule will address all comments submitted and substantive differences incorporated will be explained.

Administrative Requirements

This regulation has been drafted and reviewed in accordance with Executive Order 12866, section 1(b), Principles of Regulation. This rule is a "significant regulatory action" under Executive Order 12866, section 3(f), Regulatory Planning and Review, and accordingly this rule has been reviewed by the Office of Management and Budget.

The Assistant Attorney General for the Office of Justice Programs in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)) has reviewed this regulation and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities.

No information collection requirements are contained in this rule. Any information collection requirements contained in future application notices for programs authorized by this rule will be reviewed by the Office of Management and Budget (OMB), as is required by the provisions of the Paperwork Reduction Act, 91 U.S.C. 3504(h).

This regulation is being published as an interim final rule, without prior publication of notice and comment, and is made effective immediately, for good cause as explained below. Under 5 U.S.C. 553(a)(2), matters relating to grants are exempted from notice and comment requirements. Moreover, in this case, advance notice and comment would be impractical and contrary to the public interest. Title II, Subtitle A of the Violent Crime Control and Law Enforcement Act of 1994 requires the publication of regulations implementing the grant program within 90 days of enactment of the Act.

In order to satisfy congressional requirements and intentions of expeditious implementation, these regulations are effective immediately so that eligible states may apply for the boot camp discretionary program. Publishing a notice of proposed rulemaking and awaiting receipt of comments would significantly delay the implementation of the FY '95 boot camp grant program. Such delay would be contrary to the public interest and would contradict the congressional intent to provide immediate grant assistance.

Although OJP will proceed expeditiously with regard to the promulgation of guidelines for the fiscal year 1995 boot camp program, we are very interested in receiving public comment on the overall program and will consider all comments in preparing the final rule.

List of Subjects

Grant programs, Judicial administration.

For the reasons set out in the preamble, Title 28, Chapter I, of the Code of Federal Regulations is amended by adding a new part 91 as set forth below.

PART 91—GRANTS FOR CORRECTIONAL FACILITIES

Subpart A—General

Sec.

Subpart B—FY 95 Correctional Boot Camp Initiative

Authority: Section 20105 of Subtitle A, Title II of the Violent Crime Control and Law Enforcement Act of 1994.

Subpart A—General

§ 91.1 Purpose.

The Attorney General, through the Assistant Attorney General for the Office of Justice Programs, will make grants to states and to states organized as multi-state compacts to construct, develop, expand, operate or improve correctional facilities, including boot camp facilities and other alternative correctional facilities that can free conventional space for the confinement of violent offenders, to:

(a) Ensure that prison space is available for the confinement of violent offenders; and

(b) Implement truth in sentencing laws for sentencing violent offenders.

§ 91.2 Definitions.

(a) *Violent Offender*—[Reserved]

(b) *Serious Drug Offense* means an offense involving manufacturing, distributing, or possessing with intent to manufacture or distribute, a controlled substance [as defined in Section 102 of the Controlled Substances Act (21 U.S.C. 802)], for which a maximum term of imprisonment of 10 years or more is prescribed by state law.

(c) *Part 1 Violent Crimes* means murder and non-negligent manslaughter, forcible rape, robbery, and aggravated assault as reported to the Federal Bureau of Investigation for purposes of the Uniform Crime Reports. If such data is unavailable, Bureau of Justice Statistics (BJS) publications may be utilized. See, e.g., "Census of State and Federal Correctional Facilities, 1990." ("Part 1 Violent Crimes" are defined here solely as the statutorily prescribed basis for the formula allocation of funding.)

(d) *Recipient* means individual states or multi-state compacts awarded funds under this Part.

(e) *State* means a State, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, American Samoa, Guam and the Northern Mariana Islands.

(f) *Comprehensive Correctional Plan* means a plan which represents an integrated approach to the management and operation of adult and juvenile correctional facilities and programs and which includes diversion programs, particularly drug diversion programs, community corrections programs, a prisoner screening and security classification system, appropriate professional training for corrections officers in dealing with violent offenders, prisoner rehabilitation and

treatment programs, prisoner work activities (including to the extent practicable, activities relating to the development, expansion, modification, or improvement of correctional facilities) and job skills programs, educational programs, a pre-release prisoner assessment to provide risk reduction management, post-release assistance and an assessment of recidivism rates.

(g) *Correctional facilities* includes boot camps and other alternative correctional facilities for adults or juveniles that can free conventional bed space for the confinement of violent offenders.

(h) *Boot camp* means a corrections program for adult or juvenile offenders of not more than six-months confinement (not including time in confinement prior to assignment to the boot camp) involving:

(1) Assignment for participation in the program, in conformity with state law, by prisoners other than prisoners who have been convicted at any time for a violent felony;

(2) Adherence by inmates to a highly regimented schedule that involves strict discipline, physical training, and work;

(3) Participation by inmates in appropriate education, job training, and substance abuse counseling or treatment; and

(4) Post-incarceration aftercare services for participants that are coordinated with the program carried out during the period of imprisonment.

(i) *Truth in sentencing laws* means laws that:

(1) Ensure that violent offenders serve a substantial portion of sentences imposed;

(2) Are designed to provide sufficiently severe punishment for violent offenders, including violent juvenile offenders; and

(3) The prison time served is appropriately related to the determination that the inmate is a violent offender and for a period of time deemed necessary to protect the public.

§ 91.3 General Eligibility Requirements.

(a) Recipients must be individual states, or states organized as multi-state compacts.

(b) Application Requirements. To be eligible to receive either a formula or a discretionary grant under Subtitle A, an applicant must submit an application which includes:

(1) Assurances that the state(s) have implemented, or will implement, correctional policies and programs, including truth in sentencing laws. No specific requirements for complying with this condition are prescribed by this interim rule for fiscal 1995 funding because of the need for further review of the status of truth in sentencing laws and the impact and needs requirements relating to reform in state systems.

(2) Assurances that the state(s) have implemented or will implement policies that provide for the recognition of the rights and needs of crime victims.

States are not required to adopt any specific set of victims rights measures for compliance, but the adoption by a state of measures which are comparable to or exceed those applied in federal proceedings will be deemed sufficient compliance for eligibility for funding. If the state has not adopted victims rights measures which are comparable to or exceed federal law, the adequacy of compliance will be determined on a case-by-case basis. States will be afforded a reasonable amount of time to achieve compliance. States may comply with this condition by providing recognition of the rights and needs of crime victims in the following areas:

(i) providing notice to victims concerning case and offender status;

(ii) providing an opportunity for victims to be present at public court proceedings in their cases;

(iii) providing victims the opportunity to be heard at sentencing and parole hearings;

(iv) providing for restitution to victims; and

(v) establishing administrative or other mechanisms to effectuate these rights.

(3) Assurances that funds received under this section will be used to construct, develop, expand, operate or improve correctional facilities to ensure that secure space is available for the confinement of violent offenders.

(4) Assurances that the state(s) has a comprehensive correctional plan in accordance with the definition elements in § 91.2. If the state(s) does not have an adequate comprehensive correctional plan, technical assistance will be available for compliance. States will be afforded a reasonable amount of time to develop their plans.

(5) Assurances that the state(s) has involved counties and other units of local government, when appropriate, in the construction, development, expansion, modification, operation or improvement of correctional facilities designed to ensure the incarceration of violent offenders and that the state(s) will share funds received with counties and other units of local government, taking into account the burden placed on these units of government when they are required to confine sentenced prisoners because of overcrowding in state prison facilities.

(6) Assurances that funds received under this section will be used to supplement, not supplant, other federal, state, and local funds.

(7) Assurances that the state(s) has implemented, or will implement within 18 months after the date of the enactment of the Violent Crime Control and Law Enforcement Act of 1994 (September 13, 1994), policies to determine the veteran status of inmates and to ensure that incarcerated veterans receive the veterans benefits to which they are entitled.

(8) Assurances that correctional facilities will be made accessible to persons conducting investigations under the Civil Rights of Institutionalized Persons Act (CRIPA), 42 U.S.C. 1997.

(9) If applicable, documentation of the multi-state compact agreement that specifies the construction, development, expansion, modification, operation, or improvement of correctional facilities.

(10) If applicable, a description of the eligibility criteria for participation in any boot camp that is to be funded.

(c) States, and states organized as multi-state compacts, which can demonstrate affirmative responses to the assurances outlined above will be eligible to receive funds.

(d) Each state application for such funds must be accompanied by a comprehensive correctional plan. The plan shall be developed in consultation with representatives of appropriate state and local units of government, shall include both the adult and juvenile correctional systems, and shall provide an assessment of the state and local correctional needs, and a long-range implementation strategy for addressing those needs.

(e) Local units of government, i.e., any city, county, town, township, borough, parish, village or other general purpose subdivision of a state, or Indian tribe which performs law enforcement functions as determined by the secretary of the Interior, are in turn eligible to receive subgrants from a participating state(s). Such subgrants shall be made for the purpose(s) of carrying out the implementation strategy, consistent with state(s) comprehensive correctional plan.

(f) In awarding grants, consideration shall be given to the special burden placed on states which incarcerate a substantial number of inmates who are in the United States illegally. States will not be required to submit additional information on numbers of criminal aliens. The Bureau of Justice Assistance (BJA) and the Immigration and Naturalization Service (INS) are currently working together to implement the State Criminal Alien

Assistance Program (SCAAP) to assist the states with the costs of incarcerating criminal aliens. The Office of Justice Programs will coordinate with the SCAAP program to obtain the relevant information.

§ 91.4. Truth in Sentencing Incentive Grants.

(a) Half of the total amount of funds appropriated to carry out Subtitle A for each of the fiscal years 1996, 1997, 1998, 1999 and 2000 will be made available for Truth in Sentencing Incentive Grants.

(b) Eligibility. To be eligible to receive such a grant, a state, or states organized as multi-state compacts, must meet the requirements of § 91.3 and must demonstrate that the state(s)—

(1) has in effect laws which require that persons convicted of violent crimes serve not less than 85% of the sentence imposed; or

(2) Since 1993—

(i) has increased the percentage of convicted violent offenders sentenced to prison;

(ii) has increased the average prison time which will be served in prison by convicted violent offenders sentenced to prison;

(iii) has increased the percentage of sentence which will be served in prison by violent offenders sentenced to prison; and

(iv) has in effect at the time of application laws requiring that a person who is convicted of a violent crime shall serve not less than 85% of the sentence imposed if—

(A) the person has been convicted on 1 or more prior occasions in a court of the United States or of a state of a violent crime or a serious drug offense; and

(B) each violent crime or serious drug offense was committed after the defendant's conviction of the preceding violent crime or serious drug offense.

(c) Formula Allocation. The amount available to carry out this section for any fiscal year will be allocated to each eligible state in the ratio that the number of Part 1 violent crimes reported by such state to the Federal Bureau of Investigation for 1993 bears to the number of Part 1 violent crimes reported by all states to the Federal Bureau of Investigation for 1993.

(d) Transfer of Unused Funds. On September 30 of each fiscal years 1996, 1998, 1999 and 2000, the Attorney General will transfer to the funds to be allocated under the Violent Offender Incarceration Grant formula allocation (section 91.5) any funds made available to carry out this section that are not allocated to an eligible state under paragraph (b) of this section.

§ 91.5 Violent Offender Incarceration Grants.

(a) Half of the total amount of funds appropriated to carry out this subtitle for each of fiscal years 1996, 1997, 1998, 1999 and 2000 will be made available for Violent Offender Incarceration Grants.

(b) Eligibility. To be eligible to receive such a grant, a state, or states organized as multi-state compacts, must meet the requirements of section 91.3(b).

(c) Allocation of Violent Offender Incarceration Funds—

(1) Formula Allocation. 85% of the sum of the amount available for grants under this section for any fiscal year and any amount transferred as described in section 91.4(c) for that fiscal year will be allocated as follows:

(i) 0.25% will be allocated to each eligible state except that the United States Virgin Islands, American Samoa, Guam and the Northern Mariana Islands shall each be allocated 0.05%.

(ii) The amount remaining after application of paragraph (c)(1)(i) of this section will be allocated to each eligible state in the ratio that the number of Part 1 violent crimes reported by such state to the Federal Bureau of Investigation for 1993 bears to the number of Part 1 violent crimes reported by all states to the Federal Bureau of Investigation for 1993.

(2) Discretionary Allocation. Fifteen percent of the sum of the amount available for Violent Offender Incarceration Grants for any fiscal year under this subsection and any amount transferred as described in § 91.4(c) for that fiscal year will be allocated at the discretion of the Assistant Attorney General for OJP to states that have demonstrated:

(i) the greatest need for such grants, and

(ii) the ability to best utilize the funds to meet the objectives of the grant program and ensure that secure cell space is available for the confinement of violent offenders.

(d) Transfer of Unused Funds. On September 30 of each fiscal years 1996, 1997, 1998, 1999 and 2000, the Assistant Attorney General will transfer to the discretionary program under paragraph (c)(2) of this section any funds made available under paragraph (c)(1) of this section that are not allocated to an eligible state under paragraph (c)(1) of this section.

§ 91.6 Matching Requirement.

(a) The federal share of a grant received under this subtitle may not exceed 75 percent of the costs of a proposal described in an application approved under this subtitle. The matching requirement can only be met through a hard cash match, and must be satisfied by the end of the project period. A certification to that effect will be required of each recipient of grant funds and must be submitted to the Office of Justice Programs with the application.

Subpart B—FY 95 Correctional Boot Camp Initiative

§ 91.10 General.

(a) Scope of Boot Camp Program. Funding is appropriated in fiscal year 1995 to provide grants to states and multi-state compacts to plan, develop, construct and expand correctional boot camps for adults and juveniles.

(b) Adult and juvenile boot camps, referred to as "correctional boot camps," are programs that "provide a structured environment for delivering non-traditional corrections programs to criminal offenders."

(c) With respect to this program, the mandates of the Juvenile Justice and Delinquency Prevention Act (42 U.S.C. Sec. 5601 et seq.) shall apply.

(d) *Eligibility.* (1) Funding is available for both adult and juvenile boot camps. To be eligible for the funding of boot camps, states must comply with the general assurances in § 91.3(b) or demonstrate steps taken toward compliance. While the majority of assurances are applicable to the adult correctional system, those states applying for grants for juvenile boot camps must include the juvenile system in the state comprehensive correctional plan and demonstrate how construction of the boot camp will make secure space available to house violent juvenile offenders.

(2) For purposes of the FY '95 boot camp program, a "violent felony" means any crime punishable by imprisonment for a term exceeding one year, or an act of juvenile delinquency that would be punishable by imprisonment for such term if committed by an adult, that:

(i) involves the use or attempted use of a firearm or other dangerous weapon against another person, or

(ii) results in death or serious bodily injury to another person.

(3) States must document that the boot camp program does not involve more than six-months confinement (not including confinement prior to assignment to the boot camp) and includes:

(i) assignment for participation in the program, in conformity with state law, by prisoners other than prisoners who have been convicted at any time of a violent felony;

(ii) adherence by inmates to a highly regimented schedule that involves strict discipline, physical training and work;

(iii) participation by inmates in appropriate education, job training, and substance abuse counseling or treatment; and

(iv) post-incarceration aftercare services for participants that are coordinated with the program carried out during the period of imprisonment.

(4) States must provide assurances that boot camp construction will free up secure institutional bed space for violent offenders.

(e) *Evaluation.* (1) Recipients will be required to cooperate with a national evaluation team throughout the planning and implementation process. Recipients are also strongly encouraged to provide for an independent evaluation of the impact and effectiveness of the funded program.

(2) Jurisdictions are strongly encouraged to engage in systematic planning activities and to develop and evaluate boot camps as part of a comprehensive and integrated correctional plan.

(f) Limitation on funds. Grant funds cannot be used for operating costs. States will be required to show how operating expenses will be provided.

(g) Matching Requirement. The federal share of a grant received may not exceed 75 percent of the costs of the proposed boot camp program described in the appoved application. The matching requirement can only be met through a hard cash match, and must be satisfied by the end of the project period; facility operating expenses may not be used to meet the match requirement for the construction project supported. Match may be made through grantee contribution of construction-related costs. A certification to that effect will be required of each recipient of grant funds.

(h) Innovative Boot Camp Programs. Jurisdictions are encouraged to explore the development of "innovative" boot camp programs which incorporate principles based on the accumulation of research and practical experience, and reflect sound and effective correctional practice.

Laurie Robinson,

Assistant Attorney General, Office of Justice Programs

[FR Doc. 94–29963 Filed 12–6–94; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[COTP Baltimore 94–030]

RIN 2115–AE84

Regulated Navigation Area Regulation; Ice Operations in Chesapeake Bay

AGENCY: Coast Guard, DOT.

ACTION: Notice of implementation.

SUMMARY: The Ice Navigation Season Regulated Navigation Area on the northern portion of the Chesapeake Bay and its tributaries, including the Chesapeake and Delaware Canal, will be implemented December 1, 1994.

The regulations for this Regulated Navigation Area, found in 33 CFR 165.503, state that they shall be placed in effect and terminated at the direction of the Captain of the Port Baltimore by notice in the **Federal Register.**

The purpose of this Regulated Navigation Area is to provide mariners transiting the Regulated Navigation Area notice of the time period in which this regulation shall be effective. The purpose of this regulation is to enhance the safety of navigation in the affected waters by requiring operators of certain vessels, during their vessel's transit of the Regulated Navigation Area, to be aware of currently effective Ice Navigation Season Captain of the Port Orders issued by the Captain of the Port Baltimore.

EFFECTIVE DATE: This regulation is effective 12 am, December 1, 1994, and shall continue until April 30, 1995 as necessary for the safe transit of vessels in the area unless sooner terminated by the Captain of the Port. Cancellation Notice will be published in the **Federal Register.**

FOR FURTHER INFORMATION CONTACT:

Eugene Zimbalkin, Chief Warrant Officer, U.S. Coast Guard Marine Safety Office Baltimore, Customs House, 40 South Gay Street, Baltimore, Maryland 21202–4022, (410) 962–2651.

SUPPLEMENTARY INFORMATION:

Drafting Information

The drafters of this regulation are Eugene Zimbalkin, Chief Warrant Officer, project officer for the Captain of the Port, Baltimore, Maryland and Lieutenant Kathleen A. Duignan, project attorney, Fifth Coast Guard District Legal Staff.

Dated: November 29, 1994.

G.S. Cope,

Captain, U.S. Coast Guard, Captain of the Port Baltimore, Maryland.

[FR Doc. 94–30055 Filed 12–6–94; 8:45 am]

BILLING CODE 4910–14–M

33 CFR Part 165

[COTP Baltimore 94–031]

RIN 2115–AA97

Safety Zone Regulation; Inner Harbor Fireworks Display, Patapsco River, Inner Harbor, Baltimore, MD

AGENCY: Coast Guard, DOT.

ACTION: Temporary rule.

SUMMARY: With this regulation, the Coast Guard Marine Safety Office Baltimore is establishing two temporary safety zones for the New Years Eve Inner Harbor fireworks display. These safety zones are necessary to control spectator craft and to provide for the safety of life and property on U.S. navigable waters during this event. Entry into these zones is prohibited unless authorized by the Captain of the Port.

EFFECTIVE DATES: This regulation will be effective from 11 p.m. December 31, 1994 until 1 a.m. January 1, 1995 with an alternate date of January 1, 1995 from 6 p.m. to 8 p.m.

FOR FURTHER INFORMATION CONTACT: Chief Warrant Officer Eugene Zimbalkin, U.S. Coast Guard Marine Safety Office, Baltimore Custom House, 40 South Gay Street, Baltimore, Maryland 21202–4022, (410) 962–5118.

SUPPLEMENTARY INFORMATION: In accordance with 5 U.S.C. 553, a Notice of Proposed Rule Making has not been published for this regulation and good cause exists for making it effective in less than 30 days from the date of publication. The original application to hold this event was not submitted until October 25, 1994 to Coast Guard Group Baltimore. Because of the late original submission date and the additional changes there was not sufficient time remaining to publish proposed rules in advance of the event or to provide for a delayed effective date. Publishing an NPRM and delaying its effective date would be contrary to the public interest since immediate action is needed to prevent hazards to the boating community.

Background and Purpose

The Baltimore Office of Promotion requested a safety zone for the Baltimore Inner Harbor fireworks display to take place December 31, 1994/January 1,