for all of the devices, and the exemption from the good manufacturing practices requirements for the Apgar timer.

III. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). 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. As noted previously, FDA may classify devices into one of three regulatory classes according to the degree of control needed to provide reasonable assurance of safety and effectiveness. For these three devices, FDA is classifying them into class I, the lowest level of control allowed. Therefore, the agency certifies that this 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.

V. Paperwork Reduction Act of 1995

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

List of Subjects in 21 CFR Part 880

Medical devices.

Therefore, under the Federal Food, Drug and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, part 880 is amended as follows:

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

1. The authority citation for 21 CFR part 880 continues to read as follows:

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

2. Section 880.2930 is added to subpart C to read as follows:

§ 880.2930 Apgar timer.

(a) *Identification*. The Apgar timer is a device intended to alert a health care provider to take the Apgar score of a newborn infant.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 880.9. The device is also exempt from the current good manufacturing practice requirements in part 820 of this chapter, with the exception of § 820.180 of this chapter, with respect to general requirements concerning records, and § 820.198 of this chapter, with respect to complaint files.

3. Section 880.5960 is added to subpart F to read as follows:

§ 880.5960 Lice removal kit.

(a) *Identification*. The lice removal kit is a comb or comb-like device intended to remove and/or kill lice and nits from head and body hair. It may or may not be battery operated.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 880.9.

4. Section 880.6990 is added to subpart G to read as follows:

§ 880.6990 Infusion stand.

(a) *Identification*. The infusion stand is a stationary or movable stand intended to hold infusion liquids, infusion accessories, and other medical devices.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 880.9.

Dated: September 16, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–29568 Filed 11–4–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 311

OSD Privacy Program

AGENCY: Office of the Secretary, DOD.

ACTION: Final rule.

SUMMARY: The Office of the Secretary of Defense deleted an exempt system of records identified as DODDS 25, entitled DoDDS Internal Review Office Project File on June 12, 1998, 62 FR 32193. Therefore, the exemption rule is being removed.

EFFECTIVE DATE: June 12, 1998.

FOR FURTHER INFORMATION CONTACT: Mr. David Bosworth at (703) 695–0970.

SUPPLEMENTARY INFORMATION:

Executive Order 12866. It has been determined that this Privacy Act rule for the Department of Defense does not constitute 'significant regulatory action'. Analysis of the rule indicates that it does not have an annual effect on the economy of $100 million or more; does not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; does not materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; does not raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866.

Regulatory Flexibility Act. It has been determined that this Privacy Act rule for the Department of Defense does not have significant economic impact on a substantial number of small entities because it is concerned only with the administration of Privacy Act systems of records within the Department of Defense.

Paperwork Reduction Act. It has been determined that this Privacy Act rule for the Department of Defense imposes no information requirements beyond the Department of Defense and that the information collected within the Department of Defense is necessary and consistent with 5 U.S.C. 552a, known as the Privacy Act, and 44 U.S.C. Chapter 35.

List of Subjects in 32 CFR part 311

Privacy.

Accordingly, 32 CFR part 311 is amended as follows:

1. The authority citation for 32 CFR part 311 continues to read as follows:

Authority: Pub.L. 93–579, 88 Stat 1896 (5 U.S.C.552a).

2. Section 311.7, paragraph (c)(7) is removed and reserved as follows:

§ 311.7 Procedures for exemptions.

* * * * *

(c) * * *

(7) [Reserved]

* * * * *

Dated: October 30, 1998.

L. M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 98–29575 Filed 11–4–95; 8:45 am]

BILLING CODE 5000–04–F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD01–98–157]

RIN 2115–AA97

Safety Zone: Building Owners and Managers Fireworks, Hudson River, Manhattan, NY

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for the Building Owners and Managers Fireworks program located on the Hudson River, Manhattan, New York. This action is necessary to provide for the safety of life on navigable waters during the event. This action is intended to restrict vessel traffic on a portion of the Hudson River.

DATES: This rule is effective from 10 p.m. until 11:30 p.m., on Friday, November 13, 1998. There is no rain date for this event.

ADDRESSES: Documents as indicated in this preamble are available for inspection or copying at Coast Guard Activities New York, 212 Coast Guard Drive, room 205, Staten Island, New York 10305, between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays. The telephone number is (718) 354–4195.

FOR FURTHER INFORMATION CONTACT: Lieutenant (Junior Grade) A. Kenneally, Waterways Oversight Branch, Coast Guard Activities New York, at (718) 354–4195.

SUPPLEMENTARY INFORMATION:

Regulatory History

Pursuant to 5 U.S.C. 553, a notice of proposed rulemaking (NPRM) was not published for this regulation. Good cause exists for not publishing an NPRM and for making this regulation effective less than 30 days after **Federal Register** publication. Due to the date the Application for Approval of Marine Event was received, there was insufficient time to draft and publish an NPRM. Any delay encountered in this regulation's effective date would be contrary to public interest since immediate action is needed to close a portion of the waterway and protect the maritime public from the hazards associated with this fireworks display.

Background and Purpose

On September 10, 1998, Bay Fireworks submitted an application to hold a fireworks program on the waters of the Hudson River. The fireworks program is being sponsored by Chelsea Piers, New York. This regulation establishes a safety zone in all waters of the Hudson River within a 360 yard radius of the fireworks barge located in approximate position 40°44′49″N 074°01′02″W (NAD 1983), approximately 500 yards west of Pier 60, Manhattan, New York. The safety zone is in effect from 10 p.m. until 11:30 p.m. on Friday, November 13, 1998. There is no rain date for this event. The safety zone prevents vessels from transiting a portion of the Hudson River and is needed to protect boaters from the hazards associated with fireworks launched from a barge in the area. Marine traffic will still be able to transit through the eastern 150 years of the 850-yard wide Hudson River during the event. The Captain of the Port does not anticipate any negative impact on commercial traffic due to this event. Additionally, vessels are not precluded from mooring at or getting underway from Piers 59–62 or from the Piers at Castle Point, New Jersey. Public notifications will be made prior to the event via the Local Notice of Mariners and marine information broadcasts.

Regulatory Evaluation

This final rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. It has not been reviewed by the Office of Management and Budget under that Order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this final rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. This finding is based on the minimal time that vessels will be restricted from the area, that vessels are not precluded from getting underway, or mooring at, Piers 59–62 and the Piers at Castle Point, New Jersey, that vessels may safely transit to the east of the zone, and extensive advance notifications which will be made.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), the Coast Guard considered whether this rule will have a significant economic impact on a substantial number of small entities. ''Small entities'' include small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

For reasons discussed in the Regulatory Evaluation above, the Coast Guard certifies under section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601–612) that this final rule will not have a significant economic impact on a substantial number of small entities.

Collection of Information

This final rule does not provide for a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

The Coast Guard has analyzed this final rule under the principles and criteria contained in Executive Order 12612 and has determined that this final rule does not have sufficient implications for federalism to warrant the preparation of a Federal Assessment.

Unfunded Mandates

Under the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), the Coast Guard must consider whether this rule will result in an annual expenditure by state, local, and tribal governments, in the aggregate of $100 million (adjusted annually for inflation). If so, the Act requires that a reasonable number of regulatory alternatives be considered, and that from those alternatives, the least costly, most cost-effective, or least burdensome alternative that achieves the objective of the rule be selected. No state, local, or tribal government entities will be effected by this rule, so this rule will not result in annual or aggregate costs of $100 million or more. Therefore, the Coast Guard is exempt from any further regulatory requirements under the Unfunded Mandates Act.

Environment

The Coast Guard has considered the environmental impact of this final rule and concluded that under Figure 2–1, paragraph 34(g), of Commandant