rule was published and became effective.

The analysis shows that this final rule is not economically significant under Executive Order 12866 and that the agency has considered the burden to small entities. Thus, this economic analysis, together with other relevant sections of this document, serves as the agency's final regulatory flexibility analysis, as required under the Regulatory Flexibility Act. Finally, this analysis shows that the Unfunded Mandates Reform Act does not apply to the final rule because it would not result in an expenditure in any one year by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million.

IV. Paperwork Reduction Act of 1995

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

V. Environmental Impact

The agency has determined under 21 CFR 25.24(c)(6) 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.

List of Subjects in 21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 310 is amended as follows:

PART 310—NEW DRUGS

1. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b-360f, 360j, 361(a), 371, 374, 375, 379e; 42 U.S.C. 216, 241, 242(a), 262, 263b-263n.

2. Section 310.548 is added to subpart E to read as follows:

§ 310.548 Drug products containing colloidal silver ingredients or silver salts offered over-the-counter (OTC) for the treatment and/or prevention of disease.

(a) Colloidal silver ingredients and silver salts have been marketed in over-the-counter (OTC) drug products for the treatment and prevention of numerous disease conditions. There are serious and complicating aspects to many of the diseases these silver ingredients purport to treat or prevent. Further, there is a lack of adequate data to establish general recognition of the safety and effectiveness of colloidal silver ingredients or silver salts for OTC use in the treatment or prevention of any disease. These ingredients and salts include, but are not limited to, silver proteins, mild silver protein, strong silver protein, silver, silver ion, silver chloride, silver cyanide, silver iodide, silver oxide, and silver phosphate.

(b) Any OTC drug product containing colloidal silver ingredients or silver salts that is labeled, represented, or promoted for the treatment and/or prevention of any disease is regarded as a new drug within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act (the act) for which an approved application or abbreviated application under section 505 of the act and part 314 of this chapter is required for marketing. In the absence of an approved new drug application or abbreviated new drug application, such product is also misbranded under section 502 of the act.

(c) Clinical investigations designed to obtain evidence that any drug product containing colloidal silver or silver salts labeled, represented, or promoted for any OTC drug use is safe and effective for the purpose intended must comply with the requirements and procedures governing the use of investigational new drugs as set forth in part 312 of this chapter.

(d) After September 16, 1999, any such OTC drug product containing colloidal silver or silver salts initially introduced or initially delivered for introduction into interstate commerce that is not in compliance with this section is subject to regulatory action.

Dated: July 14, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–21253 Filed 8–16–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD01–99–135]

RIN 2115–AA97

Safety Zone Port of New York/New Jersey Annual Marine Events

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is removing a number of Safety Zone regulations for annual fireworks displays. This action is necessary to update the current regulations for Safety Zones. This action is intended to remove regulations for events that are now covered by other regulations.

DATES: This rule is effective August 17, 1999.

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) 354–4193.

FOR FURTHER INFORMATION CONTACT: Lieutenant J. Lopez, Waterways Oversight Branch, Coast Guard Activities New York (718) 354–4193.

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. These procedures are unnecessary because this regulation is strictly administrative in nature. This final rule merely removes obsolete sections in 33 CFR part 165. The safety zones being removed have gone through notice and comment rulemaking and are included in the First Coast Guard District Fireworks list in 33 CFR 100.114.

Background and Purpose

One June 28, 1999, the First Coast Guard District published a Final rule in the **Federal Register** (64 FR 34543) updating the regulations for Fireworks displays within the First Coast Guard District (33 CFR 100.114). The following regulations for fireworks displays from 33 CFR part 165 were added to the list in § 100.114 and are no longer required in part 165:

1. § 165.161 Safety Zone; Annual ''Fireworks on the Navesink'' Fireworks Display Navesink River, Red Bank, New Jersey.
2. § 165.166 Safety Zone; Annual Burlington Independence Day Celebration Fireworks Display, Burlington Bay, Vermont.
3. § 165.167 Safety Zone; Annual Rensselaer Festival Fireworks Display, Hudson River, New York.
4. § 165.170 Safety Zone; Heritage of Pride Fireworks Display, Hudson River, New York.

5. § 165.174 Safety Zone; Annual South Street Seaport New Year's Eve Fireworks Display, East River, New York.

6. § 165.175 Safety Zone; Annual South Street Seaport Memorial Day Fireworks Display, East River, New York.

7. § 165.178 Safety Zone; Annual North Hempstead Memorial Day Fireworks Display, Hempstead Harbor, New York.

Regulatory Evaluation

This final rule is not a significant regulatory action under section (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 fact that this regulation is strictly administrative in nature and that the regulations have gone through notice and comment rulemaking while being added to the list of First Coast Guard District fireworks displays in 33 CFR 100.114.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard considered whether this final 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 *et seq.*) 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 *et seq.*)

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 Federalism Assessment.

Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) [Pub. L. 104–4, 109 Stat. 48] requires Federal agencies to assess the effects of certain regulatory actions on State, local, and tribal governments, and the private sector. UMRA requires a written statement of economic and regulatory alternatives for rules that contain Federal mandates. A Federal mandate is a new or additional enforceable duty imposed on any State, local, or tribal government, or the private sector. If any Federal mandate causes those entities to spend, in the aggregate, $100 million or more in any one year, the UMRA analysis is required. This final rule does not impose Federal mandates on any State, or tribal governments, or the private sector.

Environment

The Coast Guard considered the environmental impact of this final rule and concluded that under figure 2–1, paragraph 34(g), of Commandant Instruction M16475.1C, this final is categorically excluded from further environmental documentation. A ''Categorical Exclusion Determination'' is available in the docket for inspection or copying where indicated under **ADDRESSES**.

List of Subjects in 33 CFR part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

Regulation

For the reasons discussed in the preamble, the Coat guard amends 33 CFR part 165 as follows:

PART 165—[AMENDED]

1. The authority citation for part 165 continues to read as follows:

(Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, 160.5; 49 CFR 1.46.

§ 165.161 [Removed]

2. Remove § 165.161.

§ 165.166 [Removed]

3. Remove § 165.166.

§ 165.167 [Removed]

4. Remove § 165.167.

§ 165.170 [Removed]

5. Remove § 165.170

§ 165.174 [Removed]

6. Remove § 165.174.

§ 165.175 [Removed]

7. Remove § 165.175.

§ 165.178 [Removed]

8. Remove § 165.178.

Dated: August 6, 1999.

R.E. Bennis,

Captain, U.S. Coast Guard, Captain of the Port, New York.

[FR Doc. 99–21269 Filed 8–16–99; 8:45 am]

BILLING CODE 4910–15–M

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AJ03

Reconsideration of Denied Claims

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This document amends the Department of Veterans Affairs' ''Medical'' regulations by adding a new section to set forth reconsideration procedures regarding claims for benefits administered by the Veterans Health Administration. These procedures would not only allow for more reflective decisions at the local level but would also allow some disputes to be resolved without the need for further appeal to the Board of Veterans' Appeals.

DATES: Effective Date: August 17, 1999.

FOR FURTHER INFORMATION CONTACT: Troy L. Baxley, Health Administration Service (10C3), Department of Veterans Affairs, 810 Vermont Avenue, NW, Washington DC 20420, telephone (202) 273–8301. (This is not a toll-free number).

SUPPLEMENTARY INFORMATION: In a document published in the **Federal Register** on February 27, 1998 (63 FR 9990), we proposed to amend the ''Medical'' regulations (38 CFR part 17) by adding a new section to set forth reconsideration procedures regarding claims for benefits administered by the Veterans Health Administration (VHA). We provided a 60-day comment period, which ended April 28, 1998. We received comments from two sources.

Both commenters asserted that the VA person rendering a decision upon reconsideration should not be the same person who rendered the original decision. We agree and have delegated the authority for making the reconsideration decision to the immediate supervisor of the initial VA decision-maker.