

None of the cost estimates in the proposed rule were corrected for the incidence of pregnant women having diseases under study (but not having been included in the studies). Hence, the cost estimates discussed in the proposed rule were overstated. The agency believes that the effect of this overstatement is relatively insignificant.

The agency is aware of industry's concerns about liability exposure associated with the inclusion of women with reproductive potential in clinical trials and the potential for harm to offspring. Although there are cases of injury to offspring of mothers who ingested experimental drugs, the inadequacy of warnings or the lack of informed consent has been an essential element of such lawsuits. The agency is not aware of any reported case in which a sponsor of an investigational drug was held liable for injuries to offspring when the sponsor provided adequate warnings and obtained fully informed consent. Therefore, the agency assumes that this rule adds nothing to current liability costs under existing law.

B. Small Entities

The analysis in the proposed rule identified protocols sponsored by small businesses. The largest additional pregnancy testing cost incurred by a small business in the reviewed protocols under the rule was \$990. Projected across all CDER and CBER review divisions and annualized, FDA expects no more than 9 protocol submissions per year from small businesses that might incur increased costs. Few small firms are likely to be affected in any given year, and most of these firms would incur no significant additional costs. Therefore, under the Regulatory Flexibility Act, the Commissioner of Food and Drugs certifies that this rule will not have a significant effect on a substantial number of small entities.

V. Environmental Impact

The agency has determined under 21 CFR 25.30(h) 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.

VI. 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.

VII. Federalism

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

List of Subjects in 21 CFR Part 312

Drugs, Exports, Imports, Investigations, Labeling, Medical research, Reporting and recordkeeping requirements, Safety.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 312 is amended as follows:

PART 312—INVESTIGATIONAL NEW DRUG APPLICATION

1. The authority citation for 21 CFR part 312 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 371; 42 U.S.C. 262.

2. Section 312.42 is amended by adding new paragraph (b)(1)(v) and by revising paragraph (b)(2)(i) to read as follows:

§ 312.42 Clinical holds and requests for modification.

* * * * *

(b) * * *

(1) * * *

(v) The IND is for the study of an investigational drug intended to treat a life-threatening disease or condition that affects both genders, and men or women with reproductive potential who have the disease or condition being studied are excluded from eligibility because of a risk or potential risk from use of the investigational drug of reproductive toxicity (i.e., affecting reproductive organs) or developmental toxicity (i.e., affecting potential offspring). The phrase "women with reproductive potential" does not include pregnant women. For purposes of this paragraph, "life-threatening illnesses or diseases" are defined as "diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted." The clinical hold would

not apply under this paragraph to clinical studies conducted:

(A) Under special circumstances, such as studies pertinent only to one gender (e.g., studies evaluating the excretion of a drug in semen or the effects on menstrual function);

(B) Only in men or women, as long as a study that does not exclude members of the other gender with reproductive potential is being conducted concurrently, has been conducted, or will take place within a reasonable time agreed upon by the agency; or

(C) Only in subjects who do not suffer from the disease or condition for which the drug is being studied.

(2) * * *

(i) Any of the conditions in paragraphs (b)(1)(i) through (b)(1)(v) of this section apply; or

* * * * *

Dated: May 24, 2000.

Jane E. Henney,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD01-00-133]

RIN 2115-AA97

Safety Zone: Fireworks Display, East River, Wards Island

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for a fireworks display located on the East River, 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 in a portion of the East River.

DATES: This rule is effective from 8:30 p.m. (e.s.t.) on June 29, 2000 until 10 p.m. (e.s.t.) on June 30, 2000.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket (CGD01-00-133) and 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) 354-4012.

FOR FURTHER INFORMATION CONTACT:

Lieutenant M. Day, Waterways Oversight Branch, Coast Guard Activities New York (718) 354-4012.

SUPPLEMENTARY INFORMATION:**Regulatory Information**

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(8), the Coast Guard finds that good cause exists for not publishing an NPRM. Good cause exists for not publishing an NPRM due to the following reasons: due to the date the Application for Approval of Marine Event was received, there was insufficient time to draft and publish an NPRM and still publish the final rule with more than 30 days before its effective date. Any delay encountered in this regulation's effective date would be contrary to public interest since immediate action is needed to close the waterway and protect the maritime public from the hazards associated with this fireworks display. This is a local event with minimal impact on the waterway, vessels may still transit through the East River during the event, the zone is only in affect for 1½ hours and vessels can be given permission to transit the zone except for about 45 minutes during this time. Additionally, vessels would not be precluded from mooring at or getting underway from commercial or recreational piers in the vicinity of the zone.

Background and Purpose

The Coast Guard has received an application to hold a fireworks program on the waters of the East River, New York. This regulation establishes a safety zone in all waters of the East River within a 150-yard radius of the fireworks land shoot in approximate position 40°46'55.5" N 073°55'33" W (NAD 1983), about 200 yards northeast of the Triborough Bridge. The safety zone is in effect from 8:30 p.m. (e.s.t.) until 10 p.m. (e.s.t.) on Thursday, June 29, 2000. If the event is cancelled due to inclement weather, then this section is effective from 8:30 p.m. (e.s.t.) until 10 p.m. (e.s.t.) on Friday, June 30, 2000. The safety zone prevents vessels from transiting a portion of the East River and is needed to protect boaters from the hazards associated with fireworks launched from shore in the area. Recreational and commercial vessel traffic will be able to transit through the eastern 430 feet of the 1060-foot wide East River during the event. This safety zone precludes the waterway users from entering only the safety zone itself. Public notifications will be made prior to the event via the Local Notice to Mariners.

This event is currently regulated under 33 CFR 100.114 as an annually occurring event on July 1st. Due to the extensive increase of marine traffic in the Port of New York/New Jersey due to OPSAIL 2000 and the International Naval Review 2000 the sponsor is changing their event date for this year.

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 zone, that vessels may still transit through the East River during the event, and advance notifications which will be made.

The size of this safety zone was determined using National Fire Protection Association and New York City Fire Department standards for 4" mortars fired from shore combined with the Coast Guard's knowledge of tide and current conditions in the area.

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 13132 and has determined that this final rule does not have implications for federalism under that Order.

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, local, 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 rule is categorically excluded from further environmental documentation. This rule fits paragraph 34(g) as it establishes a safety zone. 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 Coast 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.

2. Add temporary § 165.T01-133 to read as follows:

§ 165.T01-133 Safety Zone: Fireworks Display, East River, Wards Island.

(a) *Location.* The following area is a safety zone: All waters of the East River within a 150-yard radius of the fireworks land shoot in approximate position 40°46'55.5" N 073°55'33" W

(NAD 1983), about 200 yards northeast of the Triborough Bridge.

(b) *Effective period.* This section is effective from 8:30 p.m. (e.s.t.) until 10 p.m. (e.s.t.) on June 29, 2000. If the event is cancelled due to inclement weather, then this section is effective from 8:30 p.m. (e.s.t.) until 10 p.m. (e.s.t.) on June 30, 2000.

(c) *Regulations.*

(1) The general regulations contained in 33 CFR 165.23 apply.

(2) All persons and vessels shall comply with the instructions of the Coast Guard Captain of the Port or the designated on-scene-patrol personnel. These personnel comprise commissioned, warrant, and petty officers of the Coast Guard.

Upon being hailed by a U.S. Coast Guard vessel by siren, radio, flashing light, or other means, the operator of a vessel shall proceed as directed.

Dated: May 22, 2000.

R.E. Bennis,

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

[FR Doc. 00-13811 Filed 5-30-00; 12:39 pm]

BILLING CODE 4910-15-P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

36 CFR Part 1260

RIN 3095-AA67

Records Declassification

AGENCY: National Archives and Records Administration (NARA).

ACTION: Final rule.

SUMMARY: This rule updates NARA regulations related to declassification of national security-classified information in records transferred to NARA's legal custody. It incorporates changes resulting from Executive Order 12958, Classified National Security Information, including:

Revising the timeline for systematic review from 30 years to 25 years;

Redefining declassification responsibilities to reflect the E.O. 12958 requirement for agencies to maintain systematic review programs;

Adding requirements for agencies that elect to review their accessioned records at NARA;

Adding requirements for loaning records to agencies for declassification review; and Revising requirements for reclassification of information to meet the provisions of E.O. 12958;

The rule affects members of the public who file mandatory review requests and Federal agencies.

DATES: This rule is effective July 1, 2000.

FOR FURTHER INFORMATION CONTACT:

Nancy Allard or Shawn Morton at 301-713-7360.

SUPPLEMENTARY INFORMATION:

NARA published a notice of proposed rulemaking on February 17, 2000, at 65 FR 8077. The comment period ended on April 17, 2000. NARA received comments from 9 Federal agencies and 1 professional organization. Of the comments from the Federal agencies, 3 concurred with the proposed rule, 5 recommended clarifications or changes and 1 offered "no comment."

Following is a summary of the comments and a discussion of the changes that we made to the proposed rule to address those comments.

Automatic Declassification

One commenter stated that we should add a provision to account for the automatic declassification provisions in section 3.4 of Executive Order 12958. Executive Order 13142, issued on November 19, 1999, amended Executive Order 12958 section 3.4 to delay the application of automatic declassification for records accessioned into NARA until April 17, 2003. We have made appropriate reference to the automatic declassification requirements in the regulation.

As we reviewed §§ 1260.20 and 1260.40 to incorporate the reference, we further clarified these sections by removing the distinctions between records that are older and younger than 25 years to focus on the responsibilities for declassifying the information.

Restricted Data and Formerly Restricted Data

One Federal agency commented that the regulation does not address declassification responsibilities for nuclear-related information classified as Restricted Data and Formerly Restricted Data. This type of information is classified under the Atomic Energy Act of 1954, as amended, and is exempt from all requirements under Executive Order 12958. We added the language suggested by the commenter as § 1260.28, which specifies that only designated individuals in the Department of Energy may declassify records containing Restricted Data, and that only designated officials within the Department of Defense or the Department of Energy may declassify Formerly Restricted Data.

Mandatory Review Requests for White House Originated Information

The National Security Council recommended deleting § 1260.62 which

explains how agencies should handle mandatory review requests for White House originated materials from a past administration that are in their custody. This section would have required agencies to forward the request, copies of the requested records, and a recommendation to grant or deny the request to the Archivist. The Archivist would then decide whether or not to declassify the information. The commenter noted that Federal agencies do not segregate White House originated information in their custody from their Federal records, and, therefore, follow the process for responding to Mandatory Review and FOIA requests for Federal records. We have accepted the comment after consulting with the Information Security Oversight Office.

Referring Documents Back to Agencies for Declassification Determinations

One Federal agency commented that § 1260.50 should be modified in several ways. The commenter pointed out that at times, the association of an agency with a particular document can be in itself a classified fact requiring protection. NARA currently does not tell requesters which agencies it has referred documents to. We have modified § 1260.50(d) according to the commenter's suggestion to clarify this existing practice.

The agency also offered alternative language in this section to clarify when NARA would send a document back to an agency for declassification. The commenter suggested that we insert the phrase, "Where the originating agency has not provided systematic declassification guidance, or where there is a question regarding the declassification guidance provided" at the beginning of the second sentence in § 1260.50(b). We have accepted this comment with modification. We cannot specify that we will refer the information only if we are missing guidance from the originating agency. When NARA declassifies information using agency systematic guidance, we must use the guidance of every agency that has equities in the information. If we do not have guidance from an agency that has equities in the information, even when it is not the originating agency, we review the information using the guidance that we do have, and then refer the information to the agency(ies) for which we do not have guidance for final action.

Appeals

We received a comment that NARA should act as the recipient for all appeals for adverse declassification decisions from other agencies. The