

those that are outdated or otherwise in need of reform." The first results of FDA's efforts in implementing the President's plan were published in the Federal Register of October 13, 1995 (60 FR 53480). That document identified the regulations that FDA was proposing to eliminate, and the Centers within the agency responsible for those regulations.

The agency received no comments on the proposed revocation of regulations administered by the Center for Devices and Radiological Health (CDRH). This final rule will finalize the proposed revocation of the following regulations administered by CDRH:

II. Section-by-Section Analysis

1. Section 801.403 *Specific medical devices; recommended warning and caution statements* (21 CFR 801.403). This regulation recommends certain warning and caution statements for: Denture reliners, pads, and cushions; denture repair kits; infrared generators (including heating pads); insulin syringes; mechanical massagers and vibrators; steam or turkish baths; and ultraviolet generators. This section does not contain specific requirements and will therefore be removed from the Code of Federal Regulations (CFR).

2. Section 801.408 *Pessaries for intracervical and intrauterine use* (21 CFR 801.408). This section contains information that can be more appropriately given as statements of policy and will therefore be removed from the CFR.

3. Section 801.427 *Professional and patient labeling for intrauterine contraceptive devices* (21 CFR 801.427). This regulation is no longer necessary because these devices are no longer being marketed. If any intrauterine contraceptive devices are approved in the future, the labeling will be approved during the premarket approval process. This regulation will therefore be removed from the CFR.

III. 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 removes unnecessary labeling regulations, the agency certifies that the 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.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(ii) 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 801

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 801 is amended as follows:

PART 801—LABELING

1. The authority citation for 21 CFR part 801 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 507, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 357, 360i, 360j, 371, 374).

§ 801.403 [Removed]

2. Section 801.403 *Specific medical devices; recommended warning and caution statements* is removed.

§ 801.408 [Removed]

3. Section 801.408 *Pessaries for intracervical and intrauterine use* is removed.

§ 801.427 [Removed]

4. Section 801.427 *Professional and patient labeling for intrauterine contraceptive devices* is removed.

Dated: July 11, 1996.
William K. Hubbard,
Associate Commissioner for Policy
Coordination.
[FR Doc. 96-18233 Filed 7-18-96; 8:45 am]
BILLING CODE 4160-01-F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[T.D. 8128]

Miscellaneous Provisions Relating to the Tax Treatment of Partnership Items; Procedure and Administration; OMB Control Numbers; Correction

AGENCY: Internal Revenue Service, Treasury.

ACTION: Correcting amendment.

SUMMARY: This document contains a correction to temporary regulations (T.D. 8128), which were published in the Federal Register on Thursday, March 5, 1987 (52 FR 6779) relating to certain rules for the tax treatment of partnership items.

EFFECTIVE DATE: March 5, 1987.

FOR FURTHER INFORMATION CONTACT: D. Lindsay Russell (202) 622-3050, (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The temporary regulations that are the subject of this correction is under sections 6221 thru 6233 of the Internal Revenue Code.

Need for Correction

As published, the temporary regulations (T.D. 8128) contains an error which may prove to be misleading and is in need of clarification.

List of Subjects in 26 CFR Part 301

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

Accordingly, 26 CFR part 301 is corrected by making the following correcting amendment:

PART 301—PROCEDURE AND ADMINISTRATION

Paragraph 1. The authority citation for part 301 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

§ 301.6231(a)(7)-1T [Correctly redesignated from § 301.6231(a)(7)-1]

Par. 2. Section 301.6231(a)(7)-1 is redesignated as § 301.6231(a)(7)-1T. Michael L. Slaughter,
Acting Chief, Regulations Unit, Assistant Chief Counsel (Corporate).

[FR Doc. 96-18139 Filed 7-18-96; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF TRANSPORTATION**Coast Guard****33 CFR Part 165**

[CGD09-95-018]

RIN 2115-AA97

Safety Zone: Cuyahoga River, Cleveland, OH

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing a new permanent safety zone near the mouth of the Cuyahoga River in Cleveland, Ohio. The new safety zone is to prevent the mooring of boats in the area from the Conrail No. 1 railroad bridge south for six hundred feet to the end of the lot adjacent to Fagan's Restaurant. This safety zone is required to prevent the operators of recreational vessels patronizing the entertainment industries in the river from rafting their boats outward into the federally maintained navigation channel, and thus impeding the safe passage of commercial shipping.

EFFECTIVE DATE: This rule is effective on August 19, 1996.

ADDRESSES: Unless otherwise indicated, documents referenced in this preamble are available for inspection or copying at Coast Guard Marine Safety Office, 1055 E. Ninth Street, Cleveland, OH.

FOR FURTHER INFORMATION CONTACT: Lieutenant Nathan Knapp, Project Officer and Chief of Port Operations, Captain of the Port Cleveland, 1055 E. Ninth Street, Cleveland, Ohio, 44114, (216) 522-4405.

SUPPLEMENTARY INFORMATION:**Background and Purpose**

The section of the Cuyahoga River in which this safety zone is located is heavily used by both large commercial vessels and small recreational vessels. Use of the river by large commercial vessels continues to increase rising from 770 transits in 1982 to 1,264 transits in 1987, to 1,624 transits in 1994. At the same time, businesses along the river continue to attract an increasing number of recreational vessels. Large numbers of recreational vessels raft together into the river near the many entertainment establishments and restaurants, thereby creating a hazard to themselves and to the large commercial vessels which also use this waterway, and creating an obstruction to the use of the river as a navigable channel.

In 1987, a serious collision between a commercial vessel and a recreational vessel highlighted the need to establish

some rules for the protection of safe navigation in this increasingly congested waterway. After some experimentation with temporary safety zones and an extensive process of comment and consultation with the public, including a public hearing and a study by a local workgroup made up of representatives of both the commercial and recreational interests in the local area, along with representatives of the City of Cleveland and the State of Ohio, the Coast Guard established a set of ten permanent safety zones under the standing regulation at 33 CFR 165.903 (54 FR 9776, March 8, 1989).

Since that time, the safety zones have been effective in protecting the safety of navigation without causing hardship to the local businesses along the river which serve customers from recreational vessels. However, continuing commercial development and use of the area has led to the same problem of recreational vessels rafted out into the channel and obstructing navigation in a location near the mouth of the river, around Fagan's Restaurant not covered by a safety zone. The ten foot zone prevents recreational vessels from mooring to the bulkheads. Using the same process of informal consultation with local interests and civil groups which contributed to the consideration of the prior regulations, the local Coast Guard Captain of the Port in Cleveland, Ohio, invited comments from an autonomous ad hoc working group, the Cuyahoga River Task Force 1995, which included representatives of the Flats Oxbow Association, a local civic group representing businesses in the area. The consensus of the Cuyahoga River Task Force 1995 was that congestion of recreational vessels experienced around the mouth of the river called for the creation of an additional safety zone, under the same terms and conditions, including provisions for conditional waivers of the restrictions, as the other zones established for other businesses further up the river.

In 1995, the Coast Guard published a Notice of Proposed Rulemaking (60 FR 36375) proposing the zone recommended by the task force and solicited comments from the general public. No comments were received.

Environment

The Coast Guard has considered the environmental impact of this regulation and concluded that, under section 2.B.2.c of Coast Guard Commandant Instruction M16475.1B (1994 amendments), it is categorically excluded from further environmental documentation, and the categorical

exclusion determination is filed in the docket.

Federalism

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that this regulation does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Regulatory Evaluation

This regulation is considered to be nonsignificant under Executive Order 12866 on Regulatory Planning and Review and nonsignificant under Department of Transportation regulatory policies and procedures (44 FR 11034 of February 26, 1979). The economic impact of this regulation is expected to be so minimal that a full regulatory evaluation is unnecessary. Small entities that feel this regulation is causing them to incur economic losses can petition the local Captain of the Port for a waiver, provided they can prove adequate means of preventing the rafting of boats at their businesses.

Small Entities

The Coast Guard certifies that this rule will not have a significant economic impact on a substantial number of small entities. The previous experience with the other safety zones and the local procedures worked out by local business for the management of the recreational vessels along their property in cooperation with the Flats Oxbow Association and the Coast Guard, demonstrates that the restrictions imposed for the benefit of safety can be accommodated with minimal if any effect on the local businesses. These businesses are primarily accessible from non-maritime avenues and rely on such avenues for the overwhelming majority of their patronage.

Collection of Information

This regulation will impose no collection of information requirements under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Security measures, Vessels, Waterways.

In consideration of the foregoing the Coast Guard amends part 165 of title 33, Code of Federal Regulations 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, and 160.5; and 49 CFR 1.46.

2. In section 165.903, paragraphs (a)(1) through (a)(10) are redesignated as paragraphs (a)(2) through (a)(11), paragraph (a), introductory text, is revised, and a new paragraph (a)(1) is added to read as follows:

§ 165.903 Safety Zone: Cuyahoga River and Old River, Cleveland, Ohio.

(a) *Location.* The waters of the Cuyahoga River and the Old River extending ten feet into the river at the following eleven locations, including the adjacent shorelines, are safety zones, coordinates for which are based on NAD 83.

(1) From the point where the shoreline intersects longitude 81°42'24.5" W, which is the southern side of the Conrail No. 1 railroad bridge, southeasterly along the shore for six hundred (600) feet to the point where the shoreline intersects longitude 81°42'24.5" W, which is the end of the lot adjacent to Fagan's Restaurant.

* * * * *

Dated: July 2, 1996.

T.M. Close,

Lieutenant Commander, U.S. Coast Guard, Alternate Captain of the Port, Cleveland.

[FR Doc. 96-18330 Filed 7-18-96; 8:45 am]

BILLING CODE 4910-14-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 799

[OPPTS-40029; FRL-5378-3]

Technical Amendments to Test Rules and Enforceable Testing Consent Agreements/Orders

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA has approved by letter certain modifications to test standards and schedules for chemical testing programs under section 4 of the Toxic Substances Control Act (TSCA). These modifications, requested by test sponsors, will be incorporated and codified in the respective test regulations or enforceable testing consent agreements/orders. Because these modifications do not significantly alter the scope of a test or significantly change the schedule for its completion, EPA approved these requests without seeking notice and comment. EPA annually publishes a rule describing all of the modifications granted by letter for the previous year.

EFFECTIVE DATE: This rule shall take effect on July 19, 1996.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Rm. E-543B, 401 M St., SW., Washington, DC 20460, (202) 554-

1404, TDD (202) 554-0551. Internet Address: TSCA-Hotline@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a rule published in the Federal Register of September 1, 1989 (54 FR 36311), amending procedures in 40 CFR part 790 for modifying test standards and schedules for test rules and enforceable testing consent agreements/orders under section 4 of TSCA. The amended procedures allow EPA to approve requested modifications which do not alter the scope of a test or significantly change the schedule for its completion. These modifications are approved by letter without public comment. The rule also requires immediate placement of these letters in EPA's public files and publication of these modifications in the Federal Register. This document includes modifications approved from January 1, 1995 through December 31, 1995. For a detailed description of the rationale for these modifications, refer to the submitters' letters and EPA's responses in the public record for this rulemaking.

I. Discussion of Modifications

Each chemical discussed in this rule is identified by a specific CAS number and docket number. Copies of correspondence relating to specific chemical modifications may be found in docket number (OPPTS-40029) established for this rule. The following table lists all chemical-specific modifications approved from January 1, 1995 through December 31, 1995.

MODIFICATIONS TO TEST STANDARDS AND ENFORCEABLE TESTING CONSENT AGREEMENTS/ORDERS
(January 1, 1995 Through December 31, 1995)

Chemical/CAS Number	CFR Cite	Test	Modifications	Docket No
Final Rule(s). Drinking Water Contaminants. 1,1,2,2-Tetrachloroethane/CAS No. 79-34-5.	799.5075	14-day oral subacute testing	5	40029/42111J
Enforceable Testing Consent Agreement(s)/ Order(s). Bisphenol A diglycidyl ether /CAS No. 1675-54-3.	799.5000	Reproductive toxicity testing	5	40029/42168A
Cyclohexane/CAS No. 110-82-7	799.5000	90-day subchronic inhalation toxicity tests	9	40029/42094E
.....		Dermal absorption study	5,9	
.....		Dermal sensitization study	5	
.....		Acute SCOB test standard	9	
n-Butyl acetate/CAS No. 123-86-4	799.5000	In vivo hydrolysis protocol	7	40029/42138B

Modifications

1. Modify sampling schedule.
2. Change test substance (form/purity).
3. Change non-critical test procedure or condition.
4. Add satellite group for further testing.

5. Extend test or protocol deadline, delete test initiation date.
6. Clarify and/or add specific guideline requirement.
7. Alter specific guideline requirement approved for certain test(s).
8. Correct CAS No.

9. Amend test standard.
10. Neurotoxicity endpoint rule.
11. Revise protocol.

Note: Only modifications under numbers 5, 7, and 9 in the above table were approved in 1995.