Comments Invited

Although this action is in the form of a final rule and was not preceded by a notice of proposed rulemaking, 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 should 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communications received on or before the closing date for comments will be considered, and this rule may be amended or withdrawn in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of this action and determining whether additional rulemaking action is 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 action 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 No. 2001–ASW–08.'' The postcard will be date stamped and returned to the commenter.

Agency Findings

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, it is determined that this final rule will not have federalism implications under Executive Order 13132.

Further, the FAA has determined that this regulation is noncontroversial and unlikely to result in adverse or negative comments and only involves an established body of technical regulations that require frequent and routine amendments to keep them operationally current. Therefore, I certify that this regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. Since this rule involves routine matters that will only affect air traffic procedures and air navigation, it does not warrant preparation of a Regulatory Flexibility Analysis because the anticipated impact is so minimal.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854; 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9H, *Airspace Designations and Reporting Points*, dated September 1, 2000, and effective September 16, 2000, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ASW NM E5 Farmington, NM [REVISED]

Farmington, Four Corners Regional Airport, NM
(Lat. 36°44′29″N., long. 108°13′48″W.)
Farmington VORTAC
(Lat. 36°44′54″N., long. 108°05′56″W.)

That airspace extending upward from 700 feet above the surface within a 6.7-mile radius of Four Corners Regional Airport, and within 2.4 miles each side of the 086° radial of the Farmington VORTAC extending from the 6.7-mile radius to 13.4 miles east of the airport and within 1.6 miles each side of the 266° radial of the Farmington VORTAC extending from the 6.7-mile radius to 11.9 miles west of the airport; and that airspace extending from 1,200 feet above the surface bounded by a line extending from lat. 37°04′00″N., long. 108°56′54″W.; to lat. 37°04′00″N., long. 108°27′03″W.; thence clockwise within a 25.5-mile radius of the Farmington VORTAC to lat. 37°00′00″N., long. 107°40′18″W.; to lat. 37°00′00″N., long. 107°12′58″W.; thence clockwise within a 45.1-mile radius of the Farmington VORTAC to point of beginning; excluding that airspace within the Durango, CO, Class E airspace area and that airspace within and underlying the Crownpoint, NM, Class E airspace area.

* * * * *

Issued in Fort Worth, TX, on April 6, 2001.

Robert N. Stevens,

Acting Manager, Air Traffic Division, Southwest Region.

[FR Doc. 01–10131 Filed 4–23–01; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 159

[T.D. 01–24]

RIN 1515–AC30

Foreign Repairs to American Vessels; Correction

AGENCY: U.S. Customs Service, Department of the Treasury.

ACTION: Final rule; correction.

SUMMARY: This document contains a correction to the final regulations (T.D. 01–24), which were published in the **Federal Register** on Monday, March 26, 2001. The regulations related to the requirements regarding the declaration, entry, assessment of duty and processing of petitions for relief from duty for vessels of the United States which undergo foreign shipyard operations.

EFFECTIVE DATE: April 25, 2001.

FOR FURTHER INFORMATION CONTACT: Russell A. Berger, Regulations Branch, (202–927–1605).

SUPPLEMENTARY INFORMATION:

Background

The final regulations regarding foreign repairs to American vessels were published as T.D. 01–24 in the **Federal Register** (66 FR 16392) on Monday, March 26, 2001. In particular, these final regulations set forth the requirements regarding the declaration, entry, assessment of duty and processing of petitions for relief from duty for vessels of the United States which undergo foreign shipyard operations. The final rule document contained an error which could prove to

be misleading and is in need of clarification.

Need for Correction

Specifically, the final rule document amended the authority citation for part 159, Customs Regulations (19 CFR part 159), by moving specific authority citations for certain regulatory sections in the part to the authority citation section set forth at the beginning of the part from parenthetical references set forth immediately following the text of the particular sections. However, it has come to Customs attention that these same changes relating to the authority citation for part 159 were previously made in an interim rule document that was published in the **Federal Register** (64 FR 56433) on October 20, 1999, as T.D. 99–75.

Correction of Publication

Accordingly, the publication on March 26, 2001, of the final regulations concerning foreign repairs to American vessels (T.D. 01–24) (FR Doc. 01–7325) is corrected as follows:

1. On page 16399, in the third column, under the heading, ''PART 159—LIQUIDATION OF DUTIES'', correct amendatory instruction number 1 to read: ''The authority citation for part 159 continues to read as follows:''

2. On page 16400, in the first column, under the heading, ''PART 159—LIQUIDATION OF DUTIES'', remove amendatory instruction number 2.

3. On page 16400, in the first and second columns, again under the heading, ''PART 159—LIQUIDATION OF DUTIES'', renumber amendatory instruction numbers 3, 4 and 5 as amendatory instruction numbers 2, 3, and 4, respectively.

Dated: April 19, 2001.

Harold M. Singer,

Chief, Regulations Branch.

[FR Doc. 01–10163 Filed 4–23–01; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 50 and 56

[Docket No. 00N–0074]

RIN 0910–AC07

Additional Safeguards for Children in Clinical Investigations of FDA-Regulated Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim rule; opportunity for public comment.

SUMMARY: The Food and Drug Administration (FDA) is issuing an interim rule to amend its regulations to provide additional safeguards for children enrolled in clinical investigations of FDA-regulated products. This interim rule is intended to bring FDA regulations into compliance with provisions of the Children's Health Act of 2000 (the Children's Health Act), which requires that within 6 months of its enactment all research involving children that is conducted, supported, or regulated by the Department of Health and Human Services (HHS) be in compliance with HHS regulations providing additional protections for children involved as subjects in research. To comply with this congressionally mandated timeframe and for other reasons described in this document, FDA is publishing this regulation as an interim rule.

FDA is requiring additional safeguards to protect children because of expected increases in the enrollment of children in clinical investigations as a result of recent pediatric initiatives. These initiatives include FDA's 1998 pediatric rule (the 1998 pediatric rule) and the pediatric provisions of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act).

DATES: This interim rule is effective April 30, 2001. Submit written comments by July 23, 2001. Submit written comments on the information collection requirements by May 24, 2001.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. Submit written comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Carol Drew, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

FDA's authority includes regulation of safety and effectiveness testing in humans of certain FDA-regulated products. FDA-regulated products include human drug and biological products, medical device products, and dietary supplements, nutritional, food additive, and foods. This rule covers safety and effectiveness testing of FDA-regulated products in children. FDA expects an increase in testing of drug and biological products in children as a result of recent initiatives in pediatric research.

A. Recent Initiatives in Pediatric Research

The 1998 pediatric rule (63 FR 66632, December 2, 1998) requires manufacturers to assess the safety and effectiveness of certain drug and biological products in pediatric patients. In the preamble to the 1998 pediatric rule, FDA stated that many drug and biological products marketed in the United States that are or could be used in children are inadequately labeled for use in pediatric patients or specific pediatric subgroups. FDA concluded that the absence of pediatric labeling information for these drug and biological products posed significant risks for children.

The 1998 pediatric rule establishes a presumption that certain drug and biological products will be studied in pediatric patients. The 1998 pediatric rule also authorizes FDA to require pediatric studies of those marketed drug and biological products that: (1) Are used in a substantial number of pediatric patients for the labeled indications, and where the absence of adequate labeling could pose significant risks to pediatric patients; or (2) would provide a meaningful therapeutic benefit over existing treatments for pediatric patients for one or more of the claimed indications, and the absence of adequate labeling could pose significant risks to pediatric patients.

The Modernization Act (Public Law 105–115) established economic incentives for manufacturers to conduct pediatric studies on drugs for which exclusivity or patent protection is available under the Drug Price Competition and Patent Term Restoration Act (Public Law 98–417) or the Orphan Drug Act (Public Law 97–414). These provisions attach 6 months of marketing exclusivity to any existing exclusivity or patent protection on a drug for which FDA has requested pediatric studies and the manufacturer has conducted such studies in accordance with the requirements of the Modernization Act.

As of October 1, 2000, FDA had received 194 proposed pediatric study requests under the exclusivity provisions of the Modernization Act and had issued 157 Written Requests for pediatric studies. A Written Request is