

acupuncture needles is available in the General Hospital Branch guidance document entitled "Guidance on the Content of Premarket Notification (510(k)) Submissions for Hypodermic Single Lumen Needles" (draft), April 1993 (Ref. 4). A copy of this guidance document is available from the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850-4307, 301-443-6597 or 800-638-2041 and FAX 301-443-8818.

Consistent with the act and the regulations, after thorough review of the clinical data submitted in the petitions, and after FDA's own literature search, on March 29, 1996, FDA sent the Acupuncture Coalition a letter (order) reclassifying acupuncture needles for general acupuncture use, and substantially equivalent devices of this generic type, from class III to class II (special controls). As required by § 860.134(b)(7), FDA is announcing the reclassification of the generic type of device. Additionally, FDA is amending part 880 (21 CFR part 880) to include the classification of acupuncture needles for the practice of acupuncture by adding new § 880.5580.

Environmental Impact

The agency has determined that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Under 21 CFR 25.24(e)(2), the reclassification of a device is categorically exempt from environmental assessment and environmental impact statement requirements. Therefore, neither an environmental assessment nor an environmental impact statement is required.

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 reclassification of devices from class III to class II will relieve some manufacturers of the cost of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs, the agency certifies that the 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.

Paperwork Reduction Act of 1995

FDA concludes that the labeling requirements in this final rule are not subject to review by the Office of Management and Budget because they do not constitute a "collection of information" under the Paperwork Reduction Act of 1995 (Pub. L. 104-13). Rather, the proposed warning statements are "public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)).

References

The following references have been placed on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. FDA letter (order) to the Acupuncture Coalition dated March 29, 1996.
2. Classification of anesthesiology devices, development of general provisions; 44 FR 63292 at 63299, November 2, 1979.
3. Anesthesiology Devices Advisory Panel's supplemental data sheet, November 30, 1976.
4. Guidance on the Content of Premarket (510(k)) Submissions for Hypodermic Single Lumen Needles (draft), April 1993.

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, 21 CFR 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: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. New § 880.5580 is added to subpart F to read as follows:

§ 880.5580 Acupuncture needle.

(a) *Identification.* An acupuncture needle is a device intended to pierce the skin in the practice of acupuncture. The device consists of a solid, stainless steel needle. The device may have a handle attached to the needle to facilitate the delivery of acupuncture treatment.

(b) *Classification.* Class II (special controls). Acupuncture needles must comply with the following special controls:

- (1) Labeling for single use only and conformance to the requirements for prescription devices set out in 21 CFR 801.109,
- (2) Device material biocompatibility, and
- (3) Device sterility.

Dated: November 20, 1996.

D. B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 96-31047 Filed 12-5-96; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 5

[Docket No. FR-4154-C-02]

RIN 2501-AC36

Revised Restrictions on Assistance to Noncitizens; Correction

AGENCY: Office of the Secretary, HUD.

ACTION: Interim rule, correction.

SUMMARY: On November 29, 1996 (61 FR 60535), HUD published an interim rule implementing the changes made to Section 214 of the Housing and Community Development Act of 1980 by the Use of Assisted Housing by Aliens Act of 1996. Section 214 prohibits HUD from making certain financial assistance available to persons other than United States citizens, nationals, or certain categories of eligible noncitizens. The November 29, 1996 interim rule incorrectly provided for a public comment due date of November 29, 1996. The public comment due date should have been January 28, 1997, 60 days after publication of the November 29, 1996 interim rule. The purpose of this document is to correct the due date for public comments in the November 29, 1996 rule.

SUPPLEMENTARY INFORMATION:

Accordingly, FR Doc. 96-30498, Revised Restrictions on Assistance to Noncitizens, published in the Federal Register on November 29, 1996 (61 FR 60535) is corrected as follows:

On page 60535, in column 3, the **DATES** section is corrected to provide that comments are due on January 28, 1997.

Dated: December 2, 1996.

Camille E. Acevedo,

Assistant General Counsel for Regulations.

[FR Doc. 96-31034 Filed 12-5-96; 8:45 am]

BILLING CODE 4210-32-P

DEPARTMENT OF TRANSPORTATION**Coast Guard****33 CFR Part 157****46 CFR Parts 31 and 35**

[CGD 91-045]

RIN 2115-AEO1

Operational Measures To Reduce Oil Spills From Existing Tank Vessels Without Double Hulls

AGENCY: Coast Guard, DOT.

AGENCY: Notice of approval.

SUMMARY: On July 30, 1996, the Coast Guard issued regulations that will require owners, masters, or operators of tank vessels of 5,000 gross tons or more that do not have double hulls and that carry oil in bulk as cargo to comply with certain operational measures. Many requirements contained in the final rule include collection-of-information provisions. This notice of approval intends to notify the public of the collection-of-information approval by the Office of Management and Budget.

DATES: This notice of approval is effective December 6, 1996. The final rule, published at 61 FR 39769, July 30, 1996, and the collection-of-information contained therein, is effective on November 27, 1996, except for §§ 157.415 and 157.420 of 33 CFR part 157, which are effective on February 1, 1997; and § 157.445 of 33 CFR part 157, which is effective on July 29, 1997. The collection-of-information contained in § 157.455(a) (5) and (6) is suspended until further notice as discussed in the partial suspension notice published on November 27, 1996 (61 FR 60189).

ADDRESSES: Unless otherwise indicated, documents referred to in this preamble are available for inspection or copying at the Office of the Executive Secretary, Marine Safety Council (G-LRA/3406)

(CGD 91-045), U.S. Coast Guard Headquarters, 2100 Second Street SW., room 3406, Washington, DC 20593-0001 between 9:30 a.m. and 2 p.m., Monday through Friday, except Federal holidays. The telephone number is (202) 267-1477.

FOR FURTHER INFORMATION CONTACT:

LCDR Suzanne Englebert, Project Manager, Office of Standards Evaluation and Development, at (202) 267-1492.

SUPPLEMENTARY INFORMATION: The final rule entitled "Operation Measures to Reduce Oil Spills from Existing Tank Vessels without Double Hulls" was published on July 30, 1996, in the Federal Register (61 FR 39769). The final rule contained requirements for bridge resource management and vessel policy and procedures, enhanced survey programs, maneuvering performance capability, and other measures aimed at reducing oil discharges from single-hull vessels.

Under the Paperwork Reduction Act (44 U.S.C. 3501, *et seq.*), the Coast Guard submitted the collection-of-information requirements to the Office of Management and Budget (OMB), who reviewed the operational measures final rule to determine whether the practical value of the information is worth the burden imposed by its collection. The Office of Management and Budget approved the collection-of-information requirements contained in the final rule entitled "Operational Measures to Reduce Oil Spills from Existing Tank Vessels without Double Hulls" through August 31, 1999. The recently assigned, valid control number is 2115-0629 for the collection-of-information requirements.

Dated: December 2, 1996.

Howard L. Hime,

Acting Director of Standards.

[FR Doc. 96-31033 Filed 12-5-96; 8:45 am]

BILLING CODE 4910-14-M

POSTAL SERVICE**39 CFR Part 111**

Domestic Mail Manual; Miscellaneous Amendments

AGENCY: Postal Service.

ACTION: Final rule.

SUMMARY: This document describes the numerous amendments consolidated in the Transmittal Letter for Issue 51 of the Domestic Mail Manual, which is incorporated by reference in the Code of Federal Regulations, see 39 CFR 111.1. These amendments reflect changes in mail preparation requirements and

miscellaneous other rules and regulations.

EFFECTIVE DATE: January 1, 1997.

FOR FURTHER INFORMATION CONTACT:

Neil Berger, (202) 268-2859.

SUPPLEMENTARY INFORMATION: The DMM, incorporated by reference in title 39, Code of Federal Regulations, part 111, contains the basic standards of the U.S. Postal Service governing its domestic mail services; descriptions of the mail classes and special services and conditions governing their use; and standards for rate eligibility and mail preparation. The document is amended and republished about every 6 months, with each issue sequentially numbered.

DMM Issue 51, the next edition of the DMM, is scheduled for release on January 1, 1997. That issue will contain substantive changes to mail preparation standards and mail classification for nonprofit rate categories for Periodicals and Nonprofit Standard Mail. These standards were published on August 15, 1996, in the Federal Register (61 FR 42478-42489), as approved on August 6, 1996, by the USPS to implement the Decision of the Governors of the Postal Service in Postal Rate Commission Docket No. MC96-2, Classification Reform II. Those standards took effect at 12:01 a.m., October 6, 1996, aligning the preparation rules adopted on July 1 for commercial mail with those for nonprofit mail.

The following excerpt from section I010, Summary of Changes, of the transmittal for DMM Issue 51 covers the minor changes not previously described in that final rule or in other interim or final rules published in the Federal Register. In addition, the revised contents of DMM Issue 51 are also presented.

Domestic Mail Manual Issue 51
Summary of Changes

Address Adjustments

F010.2.0 clarifies the policy for delivery and address list correction services provided to mailers who send mail to addresses converted by the USPS. Such mail is delivered to the correct locations for 1 year from the date when the converted addresses appear in the bimonthly USPS Address Information System (AIS) products. For up to 3 years after the conversion date, postmasters must provide manual gallery list corrections. *Effective October 1, 1996* (PB 21929 (9-26-96)).

Automation Flats Length

C820.2.3b(2) decreases from 6 to 5³/₈ inches the required length for pieces claimed at automation rates for flats if the pieces are not more than 7¹/₂ inches