using the device outweighs the risk of injury or illness from its use, taking into account the probable risk and benefits of currently available devices or alternative forms of treatment.

There are two steps to obtaining approval of a humanitarian use device. First, the applicant must submit a request for humanitarian use device designation to FDA's Office of Orphan Products Development (§ 814.100(c)(1) (21 CFR 814.100(c)(1))). Next, the applicant must submit an HDE application (§ 814.100(c)(2)). Approval of an HDE authorizes marketing of the device. Designation of a device as a humanitarian use device is not a ''major federal action'' subject to analysis under NEPA because it is a determination that a device is eligible to apply for HDE approval and is not a final determination that any particular device may be marketed. A determination that a device is eligible to apply for HDE approval cannot by itself affect the environment. (*See Alliance for Bio-Integrity* v. *Shalala*, 116 F. Supp. 2d 166, 174 (D.D.C. 2000)).

FDA is proposing to amend § 25.34 to include approval of an HDE as a category of action that does not individually or cumulatively have a significant effect on the human environment and for which neither an EA nor EIS is required. Because humanitarian use devices are limited by definition to use for treating or diagnosing diseases or conditions affecting fewer than 4,000 individuals in the United States per year, any environmental impact associated with use of a humanitarian use device is very limited. Additionally, FDA approves few HDEs (34 over the 7 years the program has been in effect), further limiting any potential environmental impact. Finally, FDA's experience in reviewing HDEs has shown that no HDE reviewed thus far has had a significant environmental impact.

IV. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this proposed 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 EIS is required.

V. Analysis of Impacts

FDA has examined the impacts of this proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). 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 proposed rule is not a significant regulatory action as defined by 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 the proposed rule provides for an exclusion from the requirement to prepare an EA or EIS and, as such, relieves a burden, the agency certifies that the proposed rule will not have significant impact on substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $110 million. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

VI. Paperwork Reduction Act of 1995

This proposed rule does not contain information collection provisions that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

List of Subjects

21 CFR Part 25

Environmental impact statements, Foreign relations, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of the Food and Drug Administration, it is proposed that 21 CFR part 25 be amended as follows:

PART 25—ENVIRONMENTAL IMPACT CONSIDERATIONS

1. The authority citation for 21 CFR part 25 continues to read as follows:

Authority: 21 U.S.C. 321–393; 42 U.S.C. 262, 263b–264; 42 U.S.C. 4321, 4332; 40 CFR parts 1500–1508; E.O. 11514, 35 FR 4247, 3 CFR, 1971 Comp., p. 531–533 as amended by E.O. 11991, 42 FR 26967, 3 CFR, 1978 Comp., p. 123–124 and E.O. 12114, 44 FR 1957, 3 CFR, 1980 Comp., p. 356–360.

2. Section 25.34 is amended by revising paragraph (b) and adding paragraph (i) to read as follows:

§ 25.34 Devices and electronic products.

* * * * *

(b) Classification or reclassification of a device under part 860 of this chapter, including the establishment of special controls, if the action will not result in increases in the existing levels of use of the device or changes in the intended use of the device or its substitutes.

* * * * *

(i) Approval of a humanitarian device exemption under subchapter H of part 814 of this chapter.

Dated: November 8, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–25974 Filed 11–23–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–138176–02]

RIN 1545–BA99

Timely Mailing Treated as Timely Filing; Hearing

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of public hearing on proposed rulemaking.

SUMMARY: This document contains a notice of public hearing on proposed regulations that would amend § 301.7502–1(e) to provide that, other than direct proof of actual delivery, a registered or certified mail receipt is the only prima facie evidence of delivery of documents that have a filing deadline prescribed by the internal revenue laws.

DATES: The public hearing will be held on Tuesday, January 11, 2005, at 10 a.m. Outlines of topics to be discussed at the hearing must be received by December 28, 2004.

ADDRESSES: The public hearing will be held in the IRS Auditorium, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC. Send submissions to CC:PA:LPD:PR (REG–138176–02), room 5203, Internal Revenue Service, POB, 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 4 p.m.

to CC:PA:LPD:PR (REG–138176–02), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC, or sent electronically, via the IRS Internet site at *http://www.irs.gov/regs.* or via the Federal eRulemaking Portal at *http://www.regulations.gov* (IRS–REG–138176–02).

FOR FURTHER INFORMATION CONTACT: Concerning submissions of comments, the hearing, and/or to be placed on the building access list to attend the hearing Sonya M. Cruse, (202) 622–4693 (not a toll-free number).

SUPPLEMENTARY INFORMATION: The subject of the public hearing is the notice of proposed rulemaking (REG–138176–02) that was published in the **Federal Register** on September 21, 2004 (69 FR 56377).

The rules of 26 CFR 601.601(a)(3) apply to the hearing. Persons who have submitted written comments and wish to present oral comments at the hearing must submit an outline of the topics to be discussed and the amount of time to be devoted to each topic (signed original and eight (8) copies) by December 28, 2004.

A period of 10 minutes is allotted to each person for presenting oral comments. After the deadline for receiving outlines has passed, the IRS will prepare an agenda containing the schedule of speakers. Copies of the agenda will be made available, free of charge, at the hearing. Because of access restrictions, the IRS will not admit visitors beyond the immediate entrance area more than 30 minutes before the hearing. For information about having your name placed on the building access list to attend the hearing, see the **FOR FURTHER INFORMATION CONTACT** section of this document.

Cynthia E. Grigsby,

Acting Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel, (Procedures and Administration).

[FR Doc. 04–26063 Filed 11–23–04; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. S–023]

RIN 1218–AC08

Updating OSHA Standards Based on National Consensus Standards

AGENCY: Occupational Safety and Health Administration (OSHA); Labor.

ACTION: Proposed rule; notice of project to update OSHA standards that are based on National Consensus Standards.

SUMMARY: OSHA is engaging in an overall effort to update OSHA standards that reference, or that include language taken directly from, outdated consensus standards. The Agency adopted many of these standards over 30 years ago under Section 6(a) of the Occupational Safety and Health Act of 1970. Most of the referenced documents have been either superseded by later versions or withdrawn by the issuing Standards Development Organization (SDO). Many are no longer in print or available to the public through the issuing SDO. The outdated versions in the OSHA standards do not reflect advances in technologies that have changed workplace safety over the last 30 years. OSHA will use a variety of regulatory approaches to update these standards, including notice and comment rulemaking, direct final rulemaking, and technical amendments.

DATES: Comments to this notice must be submitted by the following dates:

- *Hard copy:* Your comments must be submitted (postmarked or sent) by December 27, 2004.
- *Electronic transmission and facsimile:* Your comments must be sent by December 27, 2004.

ADDRESSES: You may submit written comments on this notice—identified by docket number S–023 or RIN number 1218–AC08—by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *OSHA Web Site: http://ecomments.osha.gov.* Follow the instructions for submitting comments on OSHA's Web page.
- *Fax:* If your written comments are 10 pages or fewer, you may fax them to the OSHA Docket Office at (202) 693–1648.
- *Regular mail, express delivery, hand delivery, and courier service:* Submit three copies to the OSHA Docket Office, Docket No. S–023, U.S. Department of Labor, 200 Constitution Avenue, NW., Room N–2625, Washington, DC 20210; telephone (202) 693–2350. (OSHA's TTY number is (877) 889–5627.) OSHA Docket Office hours of operation are 8:15 a.m. to 4:45 p.m., EST.

Instructions: All comments received will be posted without change to *http://dockets.osha.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received go to *http://dockets.osha.gov.*

FOR FURTHER INFORMATION CONTACT: For general information and press inquiries contact George Shaw, Acting Director, OSHA Office of Communications, Room N–3647, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone: (202) 693–1999. For technical inquiries, contact Ted Twardowski, Directorate of Standards and Guidance, Room N–3609, OSHA, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone: (202) 693–2070 or fax (202) 693–1663. Copies of this **Federal Register** notice are available from the OSHA Office of Publications, Room N–3101, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone: (202) 693–1888. Electronic copies of this **Federal Register** notice, as well as news releases and other relevant documents, are available at OSHA's Web page at *http://www.osha.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

OSHA has used consensus standards extensively as a basis for its mandatory safety and health standards since the earliest days of the Occupational Safety and Health Act of 1970 (OSH Act), 29 U.S.C. 651 *et seq.* Under Section 6(a) of the OSH Act, OSHA was given the authority for a period of 2 years to adopt both national consensus standards and established Federal standards as OSHA standards without following notice and comment rulemaking procedures. 29 U.S.C 655(a). Congress provided this authority so that OSHA would have a mechanism to begin immediately protecting the Nation's workers through mandatory standards. Using Section 6(a), the Agency adopted many consensus standards as OSHA standards.[1] OSHA adopted some of the

[1] OSHA also adopted under Section 6(a) a number of industry standards that were established Federal Standards or that were referenced in national consensus standards. For convenience only, this

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