

falling out of the device, and insufficient mechanical strength of the device and stair-climbing mechanism.

D. Any Changes to the Device Would Not Be Likely to Result in a Change in the Device's Classification

Lastly, the petition states that any changes to the devices would not be likely to result in a change in the device's classification. Specifically, the petition states that the "device has been on the market for several decades and is well characterized and understood by manufacturers and healthcare professionals." The petition then cites to section 513(g) of the FD&C Act as a mechanism to obtain the Agency's views about the classification and applicable regulatory requirements for a device that has been significantly changed. As noted above, FDA does not agree with petitioner that the subject devices are well characterized at this time, thus we cannot foresee whether, or what, changes will result in the devices' classification. While FDA agrees that section 513(g) is an appropriate mechanism to obtain the Agency's views about the classification and applicable regulatory requirements of a device, the mere fact that such an optional feedback mechanism exists may only contribute to, but would not guarantee, the reasonable assurance of safety and effectiveness of any particular device. Additionally, because FDA believes that a change to the device would be likely to result in a change in classification, FDA did not evaluate petitioner's contention that the limitations on exemption under 21 CFR 890.9 would apply to any changes that do not result in a change in classification. Thus, the petitioner's response to this factor does not weigh in favor of exemption from the requirements of premarket notification.

For all the foregoing reasons, the petition failed to demonstrate that premarket notification is not necessary to provide reasonable assurance of safety and effectiveness for the subject device type. Therefore, FDA denied the petition request for exemption from premarket notification requirements for powered patient transport, all other powered patient transport, and is issuing this order setting forth the final determination. Manufacturers of this device type must continue to submit and receive FDA clearance of a 510(k) submission before marketing their device, as well as comply with all other applicable requirements under the FD&C Act.

V. Analysis of 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

While this final order contains no new collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) is not required for this final order. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; the collections of information in 21 CFR part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR parts 800, 801, and 809, regarding labeling, have been approved under OMB control number 0910–0485.

Dated: December 3, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–26636 Filed 12–7–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1910, 1915, 1917, 1918, 1926, and 1928

[Docket No. OSHA–2021–0007]

RIN 1218–AD42

COVID–19 Vaccination and Testing; Emergency Temporary Standard

Correction

In rule document 2021–26268, appearing on page 68560 in the issue of Friday, December 3, 2021, make the following correction:

On page 68560, in the first column, in the **DATES** section, on the third and fourth lines, "86 FR 6140" should read, "86 FR 61402".

[FR Doc. C1–2021–26268 Filed 12–7–21; 8:45 am]

BILLING CODE 0099–10–D

NATIONAL FOUNDATION ON THE ARTS AND HUMANITIES

National Endowment for the Humanities

45 CFR Part 1177

RIN 3136–AA38

Claims Collection; Correction

AGENCY: National Endowment for the Humanities; National Foundation on the Arts and the Humanities.

ACTION: Direct final rule; correction.

SUMMARY: The National Endowment for the Humanities (NEH) is correcting a direct final rule that published November 24, 2021, in the **Federal Register**. The final rule revised the NEH Claims Collection regulation in accordance with the Debt Collection Improvement Act of 1996 (DCIA), as implemented by the Department of Justice (DOJ) and the Department of Treasury (Treasury) in the revised Federal Claims Collection Standards (FCCS). NEH discovered two errors after publications that could cause confusion and is correcting those errors in this document.

DATES: Effective February 22, 2022.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In FR Doc. 2021–23742, appearing in the **Federal Register** of November 24, 2021, starting on page 66964, make the following corrections:

§ 1177.9 [Corrected]

- 1. On page 66967, in the second column, designate the second paragraph (e) as paragraph (f).

§ 1177.24 [Corrected]

- 2. On page 66973 in the first column, correct the paragraph designations "a." and "b." to read as "(a)" and "(b)".

Authority: 31 U.S.C. 3711, 3716–3719; Pub. L. 104–134; 31 CFR 900–904.

Dated: December 3, 2021.

Samuel Roth,

Attorney-Advisor, National Endowment for the Humanities.

[FR Doc. 2021–26606 Filed 12–7–21; 8:45 am]

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