reorganization of its fuel-related regulations.

DATES: These rule revisions are effective on December 8, 2021.

FOR FURTHER INFORMATION CONTACT: Hampton Newsome (202–326–2889), Attorney, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Room CC–9528, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION:

I. Conforming Amendment

Recently, EPA issued amendments streamlining its fuel quality regulations (85 FR 78412 (Dec. 4, 2020)). As part of this process, EPA transferred regulations that are cross-referenced in the FTC's Fuel Rating Rule from 40 CFR part 80 to a new 40 CFR part 1090. To conform to these changes, the FTC amends § 306.10 of its Fuel Rating Rule to update a reference to EPA's ethanol labeling requirements in paragraph (a). Specifically, in 16 CFR 306.10(a), the amendment removes the reference to 40 CFR 80.1501 and adds, in its place, a reference to 40 CFR 1090.1510 (the new location of those same EPA requirements).

II. Procedural Requirements

There is good cause for adopting this final rule without advance public notice or an opportunity for public comment.[1] The amendment published in this document merely updates a cross reference to an EPA fuel quality rule referenced in the Commission's Rule. This minor technical revision does not change any substantive obligations under the Rule or create new requirements. In addition, under the Administrative Procedure Act, a final rule may be made effective without 30 days advance publication in the **Federal Register** if an agency finds good cause. Prompt adoption of this amendment is necessary to avoid confusion by updating the Rule's reference to EPA's ethanol labeling requirement. Therefore, this final rule is effective upon publication in the **Federal Register**.

The Office of Management and Budget (''OMB'') has approved the information collections contained in the Rule through September 30, 2023 (OMB Control No. 3084–0068). Since this amendment only updates a cross-reference to existing EPA requirements, it does not change the Rule's information collection requirements and does not require further OMB clearance. The requirements of the Regulatory Flexibility Act also do not apply.[2]

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a ''major rule,'' as defined by 5 U.S.C. 804(2).

List of Subjects in 16 CFR Part 306

Fuel, Fuel ratings, Gasoline, Trade practices.

For the reasons discussed in the preamble, the Federal Trade Commission amends part 306 of Title 16 of the Code of Federal Regulations as follows:

PART 306—AUTOMOTIVE FUEL RATINGS, CERTIFICATION AND POSTING

■ 1. The authority citation for part 306 continues to read as follows:

Authority: 15 U.S.C. 2801 *et seq.;* 42 U.S.C. 17021.

§ 306.10 [Amended]

■ 2. In § 306.10, in paragraph (a), remove ''40 CFR 80.1501'' and add in its place ''40 CFR 1090.1510''.

April J. Tabor,

Secretary.

[FR Doc. 2021–26558 Filed 12–7–21; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 890

[Docket No. FDA–2021–P–0424]

Medical Devices; Exemption From Premarket Notification: Powered Patient Transport, All Other Powered Patient Transport

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or Agency) is publishing an order setting forth the final determination of a petition requesting exemption from premarket notification (510(k)) requirements for the generic device type, powered patient transport, all other powered patient transport (product code ILK), classified as class II devices. These devices are motorized devices used to mitigate mobility impairment caused by injury or other disease by moving a person from one location or level to another, such as up and down flights of stairs. These devices do not include motorized three-wheeled vehicles or wheelchairs, and are distinct from the device type, powered patient transport, powered patient stairway chair lifts, which is classified separately within the same regulation (product code PCD). FDA is publishing this order in accordance with procedures established in the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: This order is effective December 8, 2021.

FOR FURTHER INFORMATION CONTACT: Dan Reed, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm.1526, Silver Spring, MD 20993–0002, 240–402–4717.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and its implementing regulations in part 807, subpart E (21 CFR part 807, subpart E) require persons who propose to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use to submit a 510(k) to FDA. The device may not be marketed until FDA finds it ''substantially equivalent'' within the meaning of section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a legally marketed device that does not require premarket approval.

On November 21, 1997, the President signed into law the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115), section 206 of which added section 510(m) to the FD&C Act, which was amended on December 13, 2016, by the 21st Century Cures Act (Cures Act) (Pub. L. 114–255). Section 510(m)(1) of the FD&C Act, requires FDA to publish in the **Federal Register** a list of each type of class II device that does not require a report under section 510(k) of the FD&C Act to provide reasonable assurance of safety and effectiveness. Section 510(m) of the FD&C Act further provides that a 510(k) will no longer be required for these devices upon the date of publication of the list in the **Federal Register**. FDA published the required lists in accordance with FDAMA and the Cures Act, in the **Federal Register** of January 21, 1998 (63 FR 3142), and July 11, 2017 (82 FR 31976), respectively.

[1] Notice and comment are not required ''when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefore in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.'' 5 U.S.C. 553(b)(3)(B).

[2] A regulatory flexibility analysis under the RFA is required only when an agency must publish a notice of proposed rulemaking for comment. *See* 5 U.S.C. 603.

Section 510(m)(2) of the FD&C Act provides that FDA may exempt a device from 510(k) requirements on its own initiative, or upon petition of an interested person, if FDA determines that a 510(k) is not necessary to provide assurance of the safety and effectiveness of the device. This section requires FDA to publish in the **Federal Register** a notice of intent to exempt a device, or of the petition, and to provide a 60-day period for public comment. Within 120 days after the issuance of the notice, FDA shall publish an order in the **Federal Register** setting forth the final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

FDA classified powered patient transport devices into class II effective December 23, 1983 (48 FR 53032, November 23, 1983). All powered patient transport devices were class II devices regulated under § 890.5150 (21 CFR 890.5150), product code ILK. In 2013, FDA amended § 890.5150 in response to a citizen petition requesting the Agency exempt permanently mounted stairway chair lifts from premarket notification requirements (78 FR 14015, March 4, 2013). In granting this request, FDA defined a subset of powered patient transport devices classified under new § 890.5150(a), identified as ''powered patient stairway chair lifts,'' product code PCD, and exempted this subset of devices from 510(k) premarket notification requirements provided certain conditions are met. The exemption did not affect ''all other powered patient transport devices'' identified under new § 890.5150(b), product code ILK. Under § 890.5150(b), a powered patient transport is a motorized device intended for use in mitigating mobility impairment caused by injury or other disease by moving a person from one location or level to another, such as up and down flights of stairs (*e.g.,* attendant-operated portable stair-climbing chairs). This generic type of device does not include motorized three-wheeled vehicles or wheelchairs.

II. Criteria for Exemption

There are a number of factors FDA may consider in order to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. FDA generally considers the following factors to determine whether premarket notification is necessary: (1) The device does not have a significant history of false or misleading claims or risks associated with inherent characteristics of the device (when making these determinations, FDA has considered the risks associated with false or misleading claims, and the frequency, persistence, cause or seriousness of the inherent risks of the device); (2) characteristics of the device necessary for its safe and effective performance are well established; (3) changes in the device that could affect safety and effectiveness will either (a) be readily detectable by users by visual examination or other means such as routine testing, before causing harm, or (b) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment; and (4) any changes to the device would not be likely to result in a change in the device's classification. FDA may also consider that, even when exempting devices, these devices would still be subject to the limitations on exemptions.

These factors are discussed in the guidance that the Agency issued on February 19, 1998, entitled ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff'' (Class II 510(k) Exemption Guidance). That guidance can be obtained through the internet at *https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080199.pdf* or by sending an email request to *CDRH-Guidance@fda.hhs.gov* to receive a copy of the document. Please use the document number 159 to identify the guidance you are requesting.

III. Petition

On April 30, 2021, FDA received a petition requesting an exemption from premarket notification for powered patient transport, all other powered patient transport (see Docket No. FDA–2021–P–0424). These devices are currently classified under § 890.5150(b), powered patient transport, all other powered patient transport. The classification regulation is split into paragraphs (a) and (b) with stairway chair lifts classified under § 890.5150(a) (product code PCD), exempt from premarket notification requirements provided certain conditions are met, while all other powered patient transport devices are classified in § 890.5150(b) (product code ILK) and remain subject to premarket notification requirements. Importantly, many different devices are classified under the generic device-type within § 890.5150(b). The FDA review focused on ''all other powered patient transport'' devices identified under § 890.5150(b), and specifically, powered portable stair-climbing chairs as described in the petition (see Docket No. FDA–2021–P–0424).

In the **Federal Register** of June 15, 2021 (86 FR 31722), FDA published a notice announcing that this petition had been received and provided opportunity for interested persons to submit comments on the petition by August 16, 2021. In the **Federal Register** of June 30, 2021 (86 FR 34770), FDA published a correction to the docket number, and, in the **Federal Register** of July 23, 2021 (86 FR 39047), subsequently extended the opportunity to submit comments on the petition to August 30, 2021. FDA received one comment that is unrelated to the petition and, thus, outside the scope of this final order.

FDA completed review of the petition and assessed the need for 510(k) clearance for this type of device against the criteria laid out in the Class II 510(k) Exemption Guidance. Based on this review, and for the reasons described in section IV, FDA has determined that premarket notification is necessary to provide a reasonable assurance of the safety and effectiveness of powered patient transport, all other powered patient transport, § 890.5150(b)(2) (product code ILK). Accordingly, FDA responded to the petition by letter dated October 19, 2021, denying the petition within the 180-day timeframe under section 510(m)(2) of the FD&C Act (see Docket No. FDA–2021–P–0424).

IV. Order

After reviewing the petition, FDA has determined that the petition failed to provide information to demonstrate that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA analyzed the petition against the criteria laid out in the Class II 510(k) Exemption Guidance.

A. The Device Does Not Have a Significant History of False or Misleading Claims or Risks Associated With Inherent Characteristics of the Device

The petition included a 5-year look at FDA medical device reports (MDRs), the FDA medical device recall database, and the FDA warning letter database using § 890.5150, product code ILK and other product codes for other device classifications, which are listed as comparable device classifications to powered patient transport, all other powered patient transport. While FDA does not have a concern related to the absence of warning letters or recalls nor, more generally, to a significant history of false or misleading claims, we do not agree that the use of the device is well

established without any reports of patient or user injury or that the device does not have a significant history of risks associated with inherent characteristics of the device solely based on a non-substantial number of MDR reports of patient or user injury. Although there have been no MDRs submitted to the Agency in the past 5 years for powered portable stair-climbing chairs under product code ILK, since September 15, 1998, FDA has received four MDRs related to powered patient transport devices including two involving serious injury to the patient, one of which involved both patient and operator injury.

The petition includes a comparison to other devices, but because these other devices and powered portable stair-climbing chairs differ in technological characteristics and safety profiles, a comparison of the number of MDRs does not provide relevant information regarding the history of risks associated with the inherent characteristics of powered patient transports under § 890.5150(b), or powered portable stair-climbing chairs more specifically.

The petition also does not consider risks associated with powered wheelchairs, which must also be analyzed given that the FDA-cleared powered portable stair-climbing chairs adhere to wheelchair consensus standards, and the unique stair-climbing functionality of the powered portable stair-climbing chair can entail a higher degree of risk related to stability concern during stair climbing and greater possiblity of human/operator error.

Additionally, analysis of MDRs for purposes of determining risks associated with inherent characteristics of the device should be viewed in light of the intended population and environment for use. As compared to other powered patient-transport devices that are used more regularly, portable stair-climbing chairs are a less common option used to transport patients, used more frequently for emergencies or when a conventional elevator is not an option. In this case, there have only been three powered portable stair-climbing chairs cleared since 1990. Thus, the risks associated with the inherent characteristics of the device, as analyzed through infrequent premarket submissions spanning over the last 30 years, cannot be proved or disapproved with reasonable certainty from the MDR system due to the lack of information about prevalence and frequency of use. Therefore, this device, as compared to the other referenced exempted devices, does not present a lower risk and a premarket review is required to provide reasonable assurance of safety and effectivenss for this device type.

B. Characteristics of the Device Necessary for Its Safe and Effective Performance Are Well Established

The petition states that characteristics of the devices necessary for their safe and effective performance are well established as demonstrated by adherence to the Quality System Regulation (QSR) (21 CFR part 820) and FDA-recognized consensus standards. To illustrate, the petition compares certain features of the subject devices to other referenced devices exempt from premarket notification. FDA does not agree that adherence to the QSR and FDA-recognized consensus standards or that industry familiarity with characteristics of the subject device alone are adequate to provide assurance of safety and effectiveness of the devices or that the features of the referenced devices exempt from premarket notification are relevant to key characteristics of the subject devices.

The consensus standards referenced in the petition apply to devices classified under § 890.5150(b), and not just the subject device, powered portable stair-climbing chair. Adherence to consensus standards, as applicable to powered portable stair-climbing devices, would not be sufficient to ensure the devices are safe and effective throughout their lifecycle because existing standards do not cover important aspects of design (*e.g.,* lift mechanism), maintenance, alteration, and repair. There are certain key design characteristics, including the stair-climbing function, that can differ and would need to be reviewed on a case-by-case basis. Additionally, FDA has only cleared three portable stair-climbing chair devices with a different design of the stair-climbing function among the manufacturers, for instance one uses a climbing foot on each of the rear wheels while another uses a motor and chain driven lifting frame mechanism. Similarly, the other devices used as comparisons have designs that differ significantly from the cleared portable stair-climbing chair devices. The petition does not provide any information to address how the safety and effectiveness of these devices, despite their design differences, can be assured through adherence to QSR and FDA recognized consensus standards even where industry may be familiar with characteristics of the subject device. Due to the small volume of devices cleared under the subject regulation and lack of an FDA-recognized consensus standards covering all the design, maintenance, alteration, and repair features of these devices, the characteristics of the devices necessary for their safe and effective performance currently are not well established through existing clearances or comparison to other device types that are currently exempt from premarket notification.

C. Changes in the Device That Could Affect Safety and Effectiveness Will Either Be Readily Detectable by Users by Visual Examination or Other Means Such as Routine Testing, Before Causing Harm or Not Materially Increase the Risk of Injury, Incorrect Diagnosis, or Ineffective Treatment

The petition states that changes in the devices that could affect safety and effectiveness will either be readily detectable by users or not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment. This statement is supported by referencing how adequate adherence to control processes under 21 CFR 820.30 and risk management under FDA recognized consensus standard International Organization for Standards (ISO 14971 will adequately control safety and effectiveness. The petition also references the general labeling requirements under 21 CFR part 801 and FDA recognized consensus standard ISO 15223–1 for labeling symbols as effective management of changes in the device that could affect safety and effectiveness detectability for users.

FDA does not agree that changes in these devices that could affect safety and effectiveness will either be readily detectable by users or not materially increase the risk of injury. Based on the powered and portable nature of these devices, and based on the designs of the three devices FDA has cleared in this category, FDA is aware of certain design characteristics that could be changed without being readily detectable by users and could increase risk of injury. For example, changes that would not necessarily be apparent to an end user could include, but would not be limited to, the device's motor, battery power source, and internal electrical and nonelectrical components. Such changes may not be fully addressed by control processes, risk management, and labeling alone in providing readily apparent detectability for device users, especially for less visible changes. Risks of injury that could be affected by changes to these characteristics include, but are not limited to, inadequate battery performance and safety, electromagnetic incompatibility (emissions and immunity) and other electrical safety, reduced resistance to ignition of upholstered parts, users

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: Elizabeth Voyatzis, Deputy General Counsel, Office of the General Counsel, National Endowment for the Humanities, 400 7th Street SW, Room 4060, Washington, DC 20506; (202) 606–8322; *gencounsel@neh.gov.*

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]

BILLING CODE 7536–01–P