PART 250—FORMS

■ 1. The authority citation for part 250 continues to read as follows:

Authority: 15 U.S.C. 717–717w, 3301–3432; 42 U.S.C. 7101–7352; 28 U.S.C. 2461 note.

■ 2. Amend § 250.16 by revising paragraph (e)(1) to read as follows:

§ 250.16 Format of compliance plan transportation services and affiliate transactions.

* * * * *

(e) *Penalty for failure to comply.* (1) Any person who transports gas for others pursuant to subpart B or G of part 284 of this chapter and who knowingly violates the requirements of §§ 358.4 and 358.5 of this chapter, this section, or § 284.13 of this chapter will be subject, pursuant to sections 311(c), 501, and 504(b)(6) of the Natural Gas Policy Act of 1978, to a civil penalty, which the Commission may assess, of not more than $1,291,894 for any one violation.

* * * * *

PART 385—RULES OF PRACTICE AND PROCEDURE

■ 3. The authority citation for part 385 is revised to read as follows:

Authority: 5 U.S.C. 551–557; 15 U.S.C. 717–717w, 3301–3432; 16 U.S.C. 791a–825v, 2601–2645; 28 U.S.C. 2461; 31 U.S.C 3701, 9701; 42 U.S.C. 7101–7352, 16441, 16451–16463; 49 U.S.C. 60502; 49 App. U.S.C. 1–85 (1988); 28 U.S.C. 2461 note (1990); 28 U.S.C. 2461 note (2015).

■ 4. Revise § 385.1504(a) to read as follows:

§ 385.1504 Maximum civil penalty (Rule 1504).

(a) Except as provided in paragraph (b) of this section, the Commission may assess a civil penalty of up to $23,331 for each day that the violation continues.

* * * * *

■ 5. Revise § 385.1602 to read as follows:

§ 385.1602 Civil penalties, as adjusted (Rule 1602).

The current inflation-adjusted civil monetary penalties provided by law within the jurisdiction of the Commission are:

(a) 15 U.S.C. 3414(b)(6)(A)(i), Natural Gas Policy Act of 1978: $1,291,894.

(b) 16 U.S.C. 823b(c), Federal Power Act: $23,331 per day.

(c) 16 U.S.C. 825n(a), Federal Power Act: $3,047.

(d) 16 U.S.C. 825o–1(b), Federal Power Act: $1,291,894 per day.

(e) 15 U.S.C. 717t–1, Natural Gas Act: $1,291,894 per day.

(f) 49 App. U.S.C. 6(10) (1988), Interstate Commerce Act: $1,352 per offense and $68 per day after the first day.

(g) 49 App. U.S.C. 16(8) (1988), Interstate Commerce Act: $13,525 per day.

(h) 49 App. U.S.C. 19a(k) (1988), Interstate Commerce Act: $1,352 per day.

(i) 49 App. U.S.C. 20(7)(a) (1988), Interstate Commerce Act: $1,352 per day.

[FR Doc. 2020–00239 Filed 1–13–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 890

[Docket No. FDA–2019–P–3347]

Medical Devices; Exemption From Premarket Notification; Class II Devices; Powered Wheeled Stretcher

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or Agency) is publishing an order granting a petition requesting exemption from premarket notification (510(k)) requirements for powered wheeled stretchers (product code INK). These devices are battery-powered tables with wheels that are intended for medical purposes for use by patients who are unable to propel themselves independently and who must maintain a prone or supine position for prolonged periods because of skin ulcers or contractures (muscle contractions). This order exempts powered wheeled stretchers, class II devices, from 510(k) requirements, subject to certain conditions for exemption. This exemption from 510(k) requirements is immediately in effect for powered wheeled stretchers. FDA is publishing this order in accordance with the section of the Federal Food, Drug, and Cosmetic Act (FD&C Act) permitting the exemption of a device from the requirement to submit a 510(k).

DATES: This order is effective January 14, 2020.

FOR FURTHER INFORMATION CONTACT: Eric Franca, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1655, Silver Spring, MD 20993–0002, 301–796–4505, *eric.franca@fda.hhs.gov.*

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 (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 (Pub. L. 114–255). Section 510(m)(1) of the FD&C Act requires FDA to publish in the **Federal Register** a notice that contains 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 of the device. 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 that list in the **Federal Register** of January 21, 1998 (63 FR 3142).

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 assure 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-calendar-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.

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to assure the safety and effectiveness of a class II device. 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'' (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 July 10, 2019, FDA received a petition requesting an exemption from premarket notification for powered wheeled stretchers (see Docket No. FDA–2019–P–3347). These devices are currently classified under 21 CFR 890.3690, powered wheeled stretchers.

In the **Federal Register** of September 16, 2019 (84 FR 48623), FDA published a notice announcing that this petition had been received and provided opportunity for interested persons to submit comments on the petition by November 15, 2019. FDA received no comments.

FDA has 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, FDA believes that premarket notification is not necessary to assure the safety and effectiveness of the device, as long as certain conditions are met. FDA believes that the risks posed by the device and the characteristics of the device necessary for its safe and effective performance are well established. FDA believes that changes in the device that could affect safety and effectiveness will be readily detectable by visual examination. Therefore, after reviewing the petition, FDA has determined that premarket notification is not necessary to assure the safety and effectiveness of powered wheeled stretchers, as long as the conditions in section IV are met. FDA responded to the petition by letter dated December 31, 2019, to inform the petitioner of this decision within the 180-day timeframe under section 510(m)(2) of the FD&C Act.

IV. Conditions for Exemption

This final order provides conditions for exemption from premarket notification for the powered wheeled stretcher.[1] The conditions that must be met for the device to be 510(k)-exempt are as follows: Appropriate analysis and nonclinical testing must demonstrate that the safety controls are adequate to ensure safe use of the device and prevent user falls from the device in the event of a device failure; appropriate analysis and nonclinical testing must demonstrate the ability of the device to withstand the rated user weight load with an appropriate factor of safety; appropriate analysis and nonclinical testing must demonstrate the longevity of the device to withstand external forces applied to the device and provide the user with an expected service life of the device; appropriate analysis and nonclinical testing must demonstrate proper environments of use and storage of the device to maximize the longevity of the device; appropriate analysis and nonclinical testing (such as outlined in appropriate FDA-recognized consensus standards) must validate electromagnetic compatibility and electrical safety; appropriate analysis and nonclinical testing (such as outlined in appropriate FDA-recognized consensus standards) must validate that the skin-contacting components of the device are biocompatible; appropriate analysis and nonclinical testing (such as outlined in appropriate FDA-recognized consensus standards) must validate the software life cycle and that all processes, activities, and tasks are implemented and documented; appropriate analysis and nonclinical testing must validate that the device components are found to be nonflammable; appropriate analysis and nonclinical testing (such as outlined in appropriate FDA-recognized consensus standards) must validate that the battery in the device performs as intended over the anticipated service life of the device; adequate labeling is provided to the user to document proper use and maintenance of the device to ensure safe use of the device in the intended use environment; and appropriate risk assessment including, but not limited to, evaluating the dimensional limits of the gaps in hospital beds and mitigation strategy to reduce entrapment.

A number of these conditions involve ''appropriate analysis and nonclinical testing,'' the details of which are outlined in, among other places, certain FDA-recognized consensus standards. The following is a list of FDA recognized consensus standards that may be used to meet the listed conditions of exemption. Specifically, those standards include FDA-recognized editions of:

- *ANSI/AAMI ES60601–1:* Medical electrical equipment—Part 1: General requirements for basic safety and essential performance
- *ANSI/AAMI/IEC 60601–1–2:* Medical electrical equipment—Part 1–2: General requirements for basic safety and essential performance—Collateral Standard: Electromagnetic disturbances—Requirements and tests
- *ISO 7176–14:* Wheelchairs—Part 14: Power and control systems for electrically powered wheelchairs and scooters—Requirements and test methods
- *ISO 7176–21:* Wheelchairs—Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers
- *ANSI/AAMI/ISO 10993–1:* Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process
- *ANSI/AAMI/ISO 10993–5:* Biological evaluation of medical devices—Part 5: Tests for in vitro cytotoxicity
- *AAMI/ANSI/ISO 10993–10:* Biological evaluation of medical devices—Part 10: Tests for irritation and skin sensitization
- *IEC 62304:* Medical device software—Software life cycle processes
- *ISO 7176–25:* Wheelchairs—Part 25: Batteries and chargers for powered wheelchairs

We also recommend you consider FDA's guidance entitled ''Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment'' when considering the appropriate risk assessment referenced in the conditions set forth above.

Firms are now exempt from 510(k) requirements for powered wheeled stretchers as long as they meet these conditions, subject to the limitations on exemption in 21 CFR 890.9. Firms must comply with the particular conditions set forth in the conditions for exemption or submit and receive clearance for a 510(k) prior to marketing.

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

This final order refers to previously approved FDA collections of

[1] FDA notes that the ''ACTION'' caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). 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 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 801 and 809, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 890

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 890 is amended as follows:

PART 890—PHYSICAL MEDICINE DEVICES

■ 1. The authority citation for part 890 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 2. In § 890.3690, revise paragraph (b) to read as follows:

§ 890.3690 Powered wheeled stretcher.

* * * * *

(b) *Classification.* Class II (performance standards). The powered wheeled stretcher is exempt from premarket notification procedures in subpart E of part 807 of this chapter, subject to § 890.9, and the following conditions for exemption:

(1) Appropriate analysis and nonclinical testing must demonstrate that the safety controls are adequate to ensure safe use of the device and prevent user falls from the device in the event of a device failure;

(2) Appropriate analysis and nonclinical testing must demonstrate the ability of the device to withstand the rated user weight load with an appropriate factor of safety;

(3) Appropriate analysis and nonclinical testing must demonstrate the longevity of the device to withstand external forces applied to the device and provide the user with an expected service life of the device;

(4) Appropriate analysis and nonclinical testing must demonstrate proper environments of use and storage of the device to maximize the longevity of the device;

(5) Appropriate analysis and nonclinical testing (such as outlined in appropriate FDA-recognized consensus standards) must validate electromagnetic compatibility and electrical safety;

(6) Appropriate analysis and nonclinical testing (such as outlined in appropriate FDA-recognized consensus standards) must validate that the skin-contacting components of the device are biocompatible;

(7) Appropriate analysis and nonclinical testing (such as outlined in appropriate FDA-recognized consensus standards) must validate the software life cycle and that all processes, activities, and tasks are implemented and documented;

(8) Appropriate analysis and nonclinical testing must validate that the device components are found to be nonflammable;

(9) Appropriate analysis and nonclinical testing (such as outlined in appropriate FDA-recognized consensus standards) must validate that the battery in the device performs as intended over the anticipated service life of the device;

(10) Adequate labeling is provided to the user to document proper use and maintenance of the device to ensure safe use of the device in the intended use environment; and

(11) Appropriate risk assessment including, but not limited to, evaluating the dimensional limits of the gaps in hospital beds, and mitigation strategy to reduce entrapment.

Dated: January 7, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–00295 Filed 1–13–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF STATE

22 CFR Parts 35, 103, 127, and 138

[Public Notice: 10992]

RIN 1400–AF00

Department of State 2020 Civil Monetary Penalties Inflationary Adjustment

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: This final rule is issued to adjust the civil monetary penalties (CMP) for regulatory provisions maintained and enforced by the Department of State. The revised CMP adjusts the amount of civil monetary penalties assessed by the Department of State based on the December 2019 guidance from the Office of Management and Budget. The new amounts will apply only to those penalties assessed on or after the effective date of this rule, regardless of the date on which the underlying facts or violations occurred.

DATES: This final rule is effective on January 14, 2020.

FOR FURTHER INFORMATION CONTACT: Alice Kottmyer, Attorney-Adviser, Office of Management, *kottmyeram@state.gov.* ATTN: Regulatory Change, CMP Adjustments, (202) 647–2318.

SUPPLEMENTARY INFORMATION: The Federal Civil Penalties Inflation Adjustment Act of 1990, Public Law 101–410, as amended by the Debt Collection Improvement Act of 1996, Public Law 104–134, required the head of each agency to adjust its CMPs for inflation no later than October 23, 1996 and required agencies to make adjustments at least once every four years thereafter. The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, Section 701 of Public Law 114–74 (the 2015 Act) further amended the 1990 Act by requiring agencies to adjust CMPs, if necessary, pursuant to a ''catch-up'' adjustment methodology prescribed by the 2015 Act, which mandated that the catch-up adjustment take effect no later than August 1, 2016. Additionally, the 2015 Act required agencies to make annual adjustments to their respective CMPs in accordance with guidance issued by the Office of Management and Budget (OMB).

Based on these statutes, the Department of State (the Department) published a final rule in June 2016 to implement the ''catch-up'' provisions; and annual updates to its CMPs in January 2017, January 2018, and March 2019 (delayed due to the government shutdown).

On December 16, 2019, OMB notified agencies that the annual cost-of-living adjustment multiplier for 2020, based on the Consumer Price Index, is 1.01764. Additional information may be found in OMB Memorandum M–20–05, at: *https://www.whitehouse.gov/wp-content/uploads/2019/12/M-20-05.pdf.* This final rule amends Department CMPs for fiscal year 2019.

Overview of the Areas Affected by This Rule

Within the Department of State (title 22, Code of Federal Regulations), this rule affects four areas:

(1) Part 35, which implements the Program Fraud Civil Remedies Act of 1986 (PFCRA), codified at 31 U.S.C. 3801–3812;