jejunum, ileocecal junction, and colon of cattle with BSE. The new scientific data confirms the presence of limited amounts of BSE infectivity in the small intestine outside of the distal ileum of classical BSE infected cattle under experimental inoculation and field conditions. The infectivity levels reported in these studies were much lower than the infectivity levels that were previously demonstrated in the distal ileum.

We have added several peer-reviewed studies (Refs. 2 to 6) to the administrative record. We invite comment on those studies.

Additionally, the European Food Safety authority (EFSA) Panel on Biological Hazards (BIOHAZ) has reviewed and evaluated new data as it relates to the BSE epidemiological situation in the European Union. We have added the EFSA documents to the administrative record as well (Refs. 7 and 8). We have evaluated the data from the studies. Only trace amounts of infectivity have been found in the proximal ileum, jejunum, ileocecal junction, and colon of cattle with naturally occurring cases of BSE. We tentatively conclude that the effect of these traces of infectivity on the risk of human or ruminant exposure to BSE in the United States is negligible. The very low levels of infectivity in parts of the intestine other than the distal ileum, the sharp decline in the prevalence of BSE worldwide, FDA's BSE-related restrictions on the contents of animal food and feed (see 21 CFR 589.2000 and 589.2001), and the extremely low prevalence of BSE within cattle in the United States due to the presence of effective mitigations and compliance with international standards suggest that the risk from parts of the intestine other than the distal ileum is extremely low. We also note that the World Organization for Animal Health (formerly known as the Office International des Epizooties or ''OIE'') has not changed its definition of SRMs to include any part of the small intestine in addition to the distal ileum. Based on this assessment, we tentatively conclude that requiring the removal of additional parts of the small intestine would not provide a measurable risk reduction compared to that already being achieved by removal of the distal ileum in all cattle and that it would be appropriate to finalize our interim final rule without changing any provisions related to the small intestine. We invite comment on this tentative conclusion.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.*

1. Terry, L.A., S. March, S.J. Ryder, et al., ''Detection of Disease Specific PrP in the Distal Ileum of Cattle Exposed Orally to the Agent of Bovine Spongiform Encephalopathy,'' *Veterinary Record,* vol. 152, pp. 387–392, 2003.
2. Balkema-Buschmann, A., C. Fast, M. Kaatz, et al., ''Pathogenesis of Classical and Atypical BSE in Cattle.'' *Preventive Veterinary Medicine,* vol. 102, pp. 112–117, 2011.
3. Hoffmann, C., M. Eiden, M. Kaatz, et al., ''BSE Infectivity in Jejunum, Ileum and Ileocaecal Junction of Incubating Cattle,'' *Veterinary Research,* vol. 42, p. 21, 2011.
4. Kimura K. and M. Haritani, ''Distribution of Accumulated Prion Protein in a Cow With Bovine Spongiform Encephalopathy,'' *The Veterinary Record,* vol. 162, pp. 822–825, 2008.
5. Okada H., Y. Iwamaru, M. Imamura, et al. ''Detection of Disease-Associated Prion Protein in the Posterior Portion of the Small Intestine Involving the Continuous Peyer's Patch in Cattle Orally Infected With Bovine Spongiform Encephalopathy Agent,'' *Transboundary and Emerging Diseases,* vol. 58(4), pp. 333–343, Aug. 2011.
6. Stack M., S.J. Moore, A. Vidal-Diez, et al. ''Experimental Bovine Spongiform Encephalopathy: Detection of PrP(SC) in the Small Intestine Relative to Exposure Dose and Age,'' *Journal of Comparative Pathology,* vol. 145, pp. 289–301, 2011.
7. ''European Food Safety Authority (EFSA) Panel on Biological Hazards (BIOHAZ),'' *EFSA Journal,* vol. 1317, pp. 1–9, 2009.
8. ''European Food Safety Authority (EFSA) Panel on Biological Hazards (BIOHAZ),'' *EFSA Journal,* vol. 9(3), p. 2104, 2011.

Dated: February 26, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–04869 Filed 3–1–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 890

[Docket No. FDA–2011–P–0882]

Medical Devices; Exemption From Premarket Notification; Class II Devices; Wheelchair Elevator

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is publishing an order granting a petition requesting exemption from premarket notification requirements for wheelchair elevator devices commonly known as inclined platform lifts and vertical platform lifts. These devices are used to provide a means for a person with a mobility impairment caused by injury or other disease to move from one level to another, usually in a wheelchair. This order exempts wheelchair elevators, class II devices, from premarket notification and establishes conditions for exemption for this device that will provide a reasonable assurance of the safety and effectiveness of the device without submission of a premarket notification (510(k)). This exemption from 510(k), subject to these conditions, is immediately in effect for wheelchair elevators. All other devices classified under FDA's wheelchair elevator regulations, including attendant-operated stair climbing devices for wheelchairs and portable platform lifts, continue to require submission of 510(k)s. FDA is publishing this order in accordance with the section of the Food, Drug, and Cosmetic Act (the FD&C Act) permitting the exemption of a device from the requirement to submit a 510(k).

DATES: This order is effective March 4, 2013.

FOR FURTHER INFORMATION CONTACT: Brian Pullin, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1554, Silver Spring, MD 20993, 301–796–6455.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and its implementing regulations (21 CFR part 807) 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. Section 510(m)(1) of the FD&C Act requires FDA, within 60 days after enactment of FDAMA, 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 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 premarket notification requirements on its own initiative, or upon petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable 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 30-day comment period. FDA must publish in the **Federal Register** its 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 provide reasonable assurance of 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, Guidance for Industry and CDRH Staff'' (Class II 510(k) Exemption Guidance). That guidance can be obtained through the Internet on the Center for Devices and Radiological Health home page at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080198.htm* or by sending an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 159 to identify the guidance you are requesting.

III. Petition

On December 2, 2011, FDA received a petition requesting an exemption from premarket notification for a wheelchair elevator commonly known as an inclined platform lift and a vertical platform lift. (See Docket No. FDA–2011–P–0882.) These devices are currently classified under 21 CFR 890.3930, *Wheelchair elevator.* On May 3, 2012, FDA responded to the petition with a letter explaining that the information provided in the petition was insufficient for the Agency to assess whether the risks posed by this type of device could be sufficiently mitigated in the absence of premarket notification requirements. To address the Agency's concerns, the petitioner submitted additional information regarding standards that could be relied upon to mitigate the device risks, which the Agency received on June 7, 2012. This restarted the 180-day clock under section 510(m)(2) of the FD&C Act. (See Class II Exemption Guidance, p. 3.)

In the **Federal Register** of June 1, 2012 (77 FR 32644), FDA published a notice announcing that this petition had been received and provided opportunity for interested persons to submit comments on the petition by July 2, 2012. FDA received one comment supporting an exemption from premarket notification for this type of device. The comment stated that these devices have been produced for many years and have a very good safety record. It noted that all of these products already need to comply with the FDA-recognized American Society of Mechanical Engineers (ASME) standard ''ASME A18.1 Safety Standard for Platform Lifts and Stairway Chairlifts'' (ASME A18.1), which provides that these products are to be built and certified to the provisions of the National Electric Code and the Canadian Standards Association (CSA)/ASME standard ''CSA B44.1/ASME A17.5 Elevator and Escalator Electrical Equipment'' for elevator and escalator electrical equipment.

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 and in 63 FR 3142, and agrees they weigh in favor of 510(k) exemption, as long as certain conditions are met. FDA agrees 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 certain types of routine analysis and nonclinical testing, such as those detailed in certain consensus standards. Therefore, after reviewing the petition, the additional information received on June 7, 2012, and the comment on the petition, FDA has determined that premarket notification is not necessary to assure the safety and effectiveness of inclined and vertical platform lifts, as long as the conditions for 510(k) exemption listed in this document are met. FDA responded to the petition by letter dated December 3, 2012, to inform the petitioner of this decision within the 180-day timeframe under section 510(m)(2) of the FD&C Act.

For clarity, this order: (1) Defines a subset of wheelchair elevators classified under § 890.3930 identified as ''permanently mounted wheelchair platform lifts'' and (2) exempts this subset of devices from premarket notification requirements provided certain conditions are met, which will be codified in this classification regulation. This order does not affect other devices classified under § 890.3930, such as attendant-operated stair climbing devices for wheelchairs and portable platform lifts, which remain subject to premarket notification requirements, and does not change the class of any of the devices classified under this regulation, which all remain in class II. These devices will remain subject to current good manufacturing practices requirements and other general controls under the statute.

IV. Conditions for Exemption

This final order provides conditions for exemption from premarket notification on appropriate testing and labeling of the device. The following conditions must be met for the device to be 510(k)-exempt: (1) Appropriate analysis and nonclinical testing (such as that outlined in the currently FDA-recognized edition of ASME A18.1 ''Safety Standard for Platform Lifts and Stairway Chair Lifts'') must demonstrate that the safety controls are adequate to prevent a free fall of the platform in the event of a device failure; (2) appropriate analysis and nonclinical testing must demonstrate the ability of the device to withstand the rated load with an appropriate factor of safety; (3) appropriate analysis and nonclinical testing must demonstrate the ability of the enclosures to prevent the user from falling from the device; and (4) appropriate analysis and nonclinical testing (such as that outlined in the currently FDA-recognized edition of AAMI/ANSI/IEC 60601–1–2, ''Medical

Electrical Equipment—Part 1–2: General Requirements for Safety—Collateral Standard: Electromagnetic Compatibility—Requirements and Tests,'' and ASME A18.1 ''Safety Standard for Platform Lifts and Stairway Chair Lifts'') must validate electromagnetic compatibility and electrical safety.

Firms are now exempt from 510(k) requirements for vertical and inclined platform lifts as long as they meet these conditions of exemption. Firms must comply with the particular mitigation measures set forth in the conditions for exemption or submit and receive clearance for a 510(k) prior to marketing.

V. 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 contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects in 21 CFR Part 890

Medical devices, Physical medicine 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 21 CFR part 890 continues to read as follows:

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

■ 2. Section 890.3930 is revised to read as follows:

§ 890.3930 Wheelchair elevator.

(a) Permanently mounted wheelchair platform lift—(1) *Identification.* A permanently mounted wheelchair platform lift is a motorized vertical or inclined platform lift device permanently installed in one location that is intended for use in mitigating mobility impairment caused by injury or other disease by providing a guided platform to move a person from one level to another, with or without a wheelchair.

(2) *Classification.* Class II. The permanently mounted wheelchair platform lift 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:

(i) Appropriate analysis and nonclinical testing (such as that outlined in the currently FDA-recognized edition of ASME A18.1 ''Safety Standard for Platform Lifts and Stairway Chair Lifts'') must demonstrate that the safety controls are adequate to prevent a free fall of the platform in the event of a device failure;

(ii) Appropriate analysis and nonclinical testing (such as that outlined in the currently FDA-recognized edition of ASME A18.1 ''Safety Standard for Platform Lifts and Stairway Chair Lifts'') must demonstrate the ability of the device to withstand the rated load with an appropriate factor of safety;

(iii) Appropriate analysis and nonclinical testing (such as that outlined in the currently FDA-recognized edition of ASME A18.1 ''Safety Standard for Platform Lifts and Stairway Chair Lifts'') must demonstrate the ability of the enclosures to prevent the user from falling from the device; and

(iv) Appropriate analysis and nonclinical testing (such as that outlined in the currently FDA-recognized editions of AAMI/ANSI/IEC 60601–1–2, ''Medical Electrical Equipment—Part 1–2: General Requirements for Safety—Collateral Standard: Electromagnetic Compatibility—Requirements and Tests,'' and ASME A18.1 ''Safety Standard for Platform Lifts and Stairway Chair Lifts'') must validate electromagnetic compatibility and electrical safety.

(b) Portable wheelchair elevators—(1) *Identification.* A portable wheelchair elevator is a motorized lift device that is not permanently mounted in one location and that is intended for use in mitigating mobility impairment caused by injury or other disease by providing a means to move a person, with or without a wheelchair, from one level to another (e.g., portable platform lifts, attendant-operated stair climbing devices for wheelchairs).

(2) *Classification.* Class II.

Dated: February 27, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–04899 Filed 3–1–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 890

[Docket No. FDA–2011–P–0804]

Medical Devices; Exemption From Premarket Notification; Class II Devices; Powered Patient Transport

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is publishing an order granting a petition requesting exemption from premarket notification requirements for powered patient transport devices commonly known as stairway chair lifts. These devices are used to assist in the transfer of a person with a mobility impairment caused by injury or other disease up and down flights of stairs. This order exempts stairway chair lifts, class II devices, from premarket notification and establishes conditions for exemption for this device that will provide a reasonable assurance of the safety and effectiveness of the device without submission of a premarket notification (510(k)). This exemption from 510(k), subject to these conditions, is immediately in effect for stairway chair lifts. All other devices classified under FDA's powered patient transport regulations, including attendant-operated portable stair-climbing chairs (which are different from wheelchairs) continue to require submission of 510(k)s. FDA is publishing this order in accordance with the section of the Food, Drug, and Cosmetic Act (the FD&C Act) permitting the exemption of a device from the requirement to submit a 510(k).

DATES: This order is effective March 4, 2013.

FOR FURTHER INFORMATION CONTACT: Brian Pullin, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1554, Silver Spring, MD 20993, 301–796–6455.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and its implementing regulations (21 CFR part 807) 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