

Westfield/Springfield, MA, Westfield-Barnes Regional Airport, VOR RWY 20, Amdt 20D  
 Westfield/Springfield, MA, Westfield-Barnes Regional Airport, VOR OR TACAN RWY 2, Amdt 4E  
 Waterville, ME, Waterville Robert Lafleur, ILS OR LOC/DME RWY 5, Amdt 4  
 Waterville, ME, Waterville Robert Lafleur, RNAV (GPS) RWY 5, Amdt 1  
 Ava, MO, Ava Bill Martin Memorial, GPS RWY 13, ORIG, CANCELED  
 Ava, MO, Ava Bill Martin Memorial, GPS RWY 31, ORIG-A, CANCELED  
 Ava, MO, Ava Bill Martin Memorial, RNAV (GPS) RWY 13, ORIG  
 Ava, MO, Ava Bill Martin Memorial, RNAV (GPS) RWY 31, ORIG  
 Ava, MO, Ava Bill Martin Memorial, Takeoff Minimums and Obstacle DP, Orig  
 Ava, MO, Ava Bill Martin Memorial, VOR-A, Amdt 3  
 Laurens, SC, Laurens County, Takeoff Minimums and Obstacle DP, Orig  
 Walterboro, SC, Lowcountry Rgnl, Takeoff Minimums and Obstacle DP, Amdt 2  
 Sturgis, SD, Sturgis Muni, RNAV (GPS) RWY 11, Amdt 1  
 Sturgis, SD, Sturgis Muni, RNAV (GPS) RWY 29, Amdt 1  
 Tullahoma, TN, Tullahoma Rgnl Arpt/WM Northern Field, SDF RWY 18, Amdt 5A, CANCELED  
 Commerce, TX, Commerce Muni, RNAV (GPS) RWY 18, Orig  
 Commerce, TX, Commerce Muni, RNAV (GPS) RWY 36, Orig  
 Siren, WI, Burnett County, Takeoff Minimums and Obstacle DP, Orig  
 [FR Doc. 2013-04571 Filed 3-1-13; 8:45 am]  
 BILLING CODE 4910-13-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 189 and 700

[Docket No. FDA-2004-N-0188] (Formerly 2004N-0081)

RIN 0910-AF47

#### Use of Materials Derived From Cattle in Human Food and Cosmetics; Reopening of the Comment Period

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Interim final rule; reopening of the comment period.

**SUMMARY:** The Food and Drug Administration (FDA or “we”) is reopening the comment period for the interim final rule entitled “Use of Materials Derived From Cattle in Human Food and Cosmetics” that published in the *Federal Register* of July 14, 2004 (69 FR 42256). The interim final rule prohibited the use of certain cattle material to address the potential risk of bovine spongiform

encephalopathy (BSE) in human food, including dietary supplements, and cosmetics. In the *Federal Register* of September 7, 2005 (70 FR 53063), we amended the interim final rule to make changes, including providing that the small intestine of cattle, formerly prohibited cattle material, could be used in human food and cosmetics if the distal ileum was removed by a specified procedure or one that the establishment could demonstrate is equally effective in ensuring complete removal of the distal ileum. Since 2005, peer-reviewed studies have been published showing the presence of infectivity in the proximal ileum, jejunum, ileocecal junction, and colon of cattle with BSE. Therefore, we are reopening the comment period for the interim final rule to give interested parties an opportunity to comment on the new studies concerning infectivity in parts of the small intestine other than the distal ileum.

**DATES:** Submit either electronic or written comments by May 3, 2013.

**ADDRESSES:** Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Johnny Braddy, Center for Food Safety and Applied Nutrition (HFS-316), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2131.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the *Federal Register* of July 14, 2004 (69 FR 42256), FDA published an interim final rule entitled “Use of Materials Derived From Cattle in Human Food and Cosmetics.” The interim final rule prohibited the use of certain cattle material to address the potential risk of BSE in human food and cosmetics. The interim final rule designated the small intestine as prohibited cattle material and prohibited its use in human food or cosmetics. In the *Federal Register* of September 7, 2005 (70 FR 53063), we amended the interim final rule to allow the use of the small intestine if the distal ileum is removed by a procedure that removes at least 80 inches of uncoiled and trimmed small intestine as measured from the ceco-colic junction and progressing proximally towards the jejunum or by a procedure that the establishment can demonstrate is equally effective in ensuring complete removal of the distal ileum.

On January 12, 2004, the U.S. Department of Agriculture, Food Safety and Inspection Service (FSIS), issued an interim final rule to designate materials that could potentially contain BSE infectivity as specified risk materials (SRMs) and prohibit their use for human food (see “Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle”; 69 FR 1862; January 12, 2004). FSIS’s interim final rule designated the distal ileum as an SRM but required that the entire small intestine be removed and disposed of as inedible to ensure the effective removal of the distal ileum. On September 7, 2005, FSIS, like FDA, amended its interim final rule to permit the use of the entire small intestine for human food if the distal ileum is removed by a procedure that removes at least 80 inches of the uncoiled and trimmed small intestine as measured from the ceco-colic junction and progressing proximally towards the jejunum or by a procedure that the establishment demonstrates is effective in ensuring complete removal of the distal ileum.

When the FDA and FSIS amendments to the interim final rules were published in 2005, BSE infectivity had been demonstrated in lymphoid tissue of the distal ileum. In naturally occurring cases, sparse immunostaining had also been observed in the myenteric plexus of the distal ileum indicating the presence of PrPSc, a TSE-specific protein (Ref. 1). Because the myenteric plexus extends throughout the small intestine, both FDA and FSIS considered that it was possible that infectivity might also exist in the myenteric plexus of the jejunum or the duodenum. We stated in our 2005 amendment to our interim final rule that if we became aware of data indicating that other portions of the small intestine harbored BSE infectivity, we would take action appropriate to the public health risk. FSIS stated in its 2005 amendment to its interim final rule that while it believed that the primary tissues of concern for spreading the BSE agent had been identified, FSIS would use the results of future studies on BSE to further refine its policies with regard to BSE (70 FR 53043 at 53047; September 7, 2005). In 2007, FSIS issued a final rule to make permanent the interim measures implemented in 2004 and amended in 2005 (72 FR 38700; July 13, 2007).

Since we amended our interim final rule in 2005 and FSIS issued its final rule in 2007, peer-reviewed studies have been published showing the presence of some infectivity in the proximal ileum,

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.*

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**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.