

do not include tallow that contains no more than 0.15 percent insoluble impurities, tallow derivatives, hides and hide-derived products, and milk and milk products.

(2) *Inspected and passed* means that the product has been inspected and passed for human consumption by the appropriate regulatory authority, and at the time it was inspected and passed, it was found to be not adulterated.

(3) *Mechanically Separated (MS)(Beef)* means a meat food product that is finely comminuted, resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle of cattle carcasses and parts of carcasses that meet the specifications contained in 9 CFR 319.5, the regulation that prescribes the standard of identity for MS (Species).

(4) *Nonambulatory disabled cattle* means cattle that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions.

(5) *Specified risk material* means the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months and older and the tonsils and distal ileum of the small intestine of all cattle.

(6) *Tallow* means the rendered fat of cattle obtained by pressing or by applying any other extraction process to tissues derived directly from discrete adipose tissue masses or to other carcass parts and tissues. Tallow must be produced from tissues that are not prohibited cattle materials or must contain not more than 0.15 percent insoluble impurities as determined by the method entitled "Insoluble Impurities" (AOCS Official Method Ca 3a-46), American Oil Chemists' Society (AOCS), 5th Edition, 1997, incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or another method equivalent in accuracy, precision, and sensitivity to AOCS Official Method Ca 3a-46. You may obtain copies of the method from the AOCS (<http://www.aocs.org>) 2211 W. Bradley Ave. Champaign, IL 61821. Copies may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records

Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(7) *Tallow derivative* means any chemical obtained through initial hydrolysis, saponification, or transesterification of tallow; chemical conversion of material obtained by hydrolysis, saponification, or transesterification may be applied to obtain the desired product.

(b) *Requirements.*

(1) No cosmetic shall be manufactured from, processed with, or otherwise contain, prohibited cattle materials.

(2) The small intestine is not considered prohibited cattle material 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 caeco-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.

(c) *Records.* Manufacturers and processors of cosmetics that are manufactured from, processed with, or otherwise contain, cattle material must make existing records relevant to compliance with this section available to FDA for inspection and copying.

(d) *Adulteration.* Failure of a manufacturer or processor to operate in compliance with the requirements of paragraph (b) or (c) of this section renders a cosmetic adulterated under section 601(c) of the act.

Dated: August 31, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 866

[Docket No. 2003D-0221]

#### Medical Devices; Immunology and Microbiology Devices; Classification of the Endotoxin Assay; Technical Amendment

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

**ACTION:** Final rule; technical amendment.

**SUMMARY:** The Food and Drug Administration (FDA) published a final rule in the **Federal Register** of October 31, 2003 (68 FR 62007). The final rule classified the endotoxin assay into class II (special controls). The agency classified the device into class II (special controls) in order to provide reasonable assurance of safety and effectiveness of the device. FDA is amending the agency's regulations to redesignate the section number listed in the Code of Federal Regulations (CFR) from § 866.3610 to § 866.3210.

**DATES:** This rule is effective September 7, 2005.

**FOR FURTHER INFORMATION CONTACT:** Freddie M. Poole, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240-276-0496 ext. 1111.

**SUPPLEMENTARY INFORMATION:** FDA has found that the endotoxin assay regulation does not reflect the correct section number listed in the CFR. Accordingly, FDA is amending the regulation in § 866.3610 (21 CFR 866.3610) to correct the error by redesignating the section number from § 866.3610 to 866.3210.

#### List of Subjects in 21 CFR Part 866

Biologics, Laboratories, 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 866 is amended as follows:

#### PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for 21 CFR part 866 continues to read as follows:

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

**§ 866.3610 [Redesignated as § 866.3210]**

■ 2. Section 866.3610 is redesignated as § 866.3210.

Dated: August 26, 2005.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

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