PART 181—NORTH AMERICAN FREE TRADE AGREEMENT

■ 26. The authority citation for part 181 is revised to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States), 1624, 3314;

PART 191—DRAWBACK

■ 27. The general authority citation for part 191 is revised to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States), 1313, 1624;

* * * * *

Dated: September 1, 2005.

Robert C. Bonner,

Commissioner, Bureau of Customs and Border Protection.

[FR Doc. 05–17662 Filed 9–6–05; 8:45 am]

BILLING CODE 9110–06–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 189 and 700

[Docket No. 2004N–0081]

RIN 0910–AF47

Use of Materials Derived From Cattle in Human Food and Cosmetics

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule and request for comments.

SUMMARY: The Food and Drug Administration (FDA) is amending the interim final rule on use of materials derived from cattle in human food and cosmetics published in the **Federal Register** of July 14, 2004. In the July 14, 2004, interim final rule, FDA designated certain materials from cattle, including the entire small intestine, as ''prohibited cattle materials'' and banned the use of such materials in human food, including dietary supplements, and in cosmetics. FDA is taking this action in response to comments received on the interim final rule. Information was provided in comments that persuaded the agency that the distal ileum, one of three portions of the small intestine, could be consistently and effectively removed from the small intestine, such that the remainder of the small intestine, formerly a prohibited cattle material, could be used for human food or cosmetics. We (FDA) are also clarifying that milk and milk products, hide and hide-derived products, and tallow derivatives are not prohibited cattle materials. Comments also led the agency to reconsider the method cited in the interim final rule for determining insoluble impurities in tallow and to cite instead a method that is less costly to use and requires less specialized equipment. FDA issued the interim final rule to minimize human exposure to materials that scientific studies have demonstrated are highly likely to contain the bovine spongiform encephalopathy (BSE) agent in cattle infected with the disease. FDA believes that the amended provisions of the interim final rule provide the same level of protection from human exposure to the agent that causes BSE as the original provisions.

DATES: The amendments to the interim final rule are effective October 7, 2005. Submit written or electronic comments on the amendments to the interim final rule by November 7, 2005. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications in 21 CFR 189.5 and 700.27 as of October 7, 2005.

ADDRESSES: You may submit comments, identified by Docket No. 2004N–0081, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.
- E-mail: *fdadockets@oc.fda.gov*. Include Docket No. 2004N–0081 and/or RIN number RIN 0910–AF47 in the subject line of your e-mail message.
- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management, Food and Drug Administration (HFA -305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No. or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm* , including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Effective Date and Opportunity for Public Comment'' heading of the **SUPPLEMENTARY INFORMATION** in section IV of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Rebecca Buckner, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1486.

SUPPLEMENTARY INFORMATION:

I. Background

On July 14, 2004, FDA issued an interim final rule entitled ''Use of Materials Derived From Cattle in Human Food and Cosmetics'' (also referred to as ''the interim final rule''), to address the potential risk of BSE in human food and cosmetics (69 FR 42256, July 14, 2004). In the interim final rule, FDA designated certain materials from cattle as ''prohibited cattle materials'' and banned the use of such materials in human food, including dietary supplements, and in cosmetics in §§ 189.5 and 700.27 (21 CFR 189.5 and 21 CFR 700.27). In the interim final rule, FDA designated the following as prohibited cattle materials: Specified risk materials (SRMs), the small intestine from all cattle, material from nonambulatory cattle, material from cattle not inspected and passed for human consumption, and mechanically separated (MS)(Beef). The materials designated as SRMs were 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 distal ileum of the small intestine and tonsils from all cattle. The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) designated the same list of materials as SRMs in its rule entitled ''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). In addition, FDA provided an alternative standard for tallow in its interim final rule. Tallow must be produced by either excluding prohibited cattle materials or, if produced using prohibited cattle materials, must contain no more than 0.15 percent insoluble impurities. Tallow derivatives were exempted from

the provisions of FDA's interim final rule.

The comment period for the interim final rule closed on October 12, 2004. After reviewing comments received on the interim final rule, FDA determined that it needed to make some changes and clarifications now, rather than waiting until we could address all of the comments in a final rule. We are amending or clarifying the interim final rule in the following five areas:

1. Use of small intestine,
2. Status of milk and milk products,
3. Status of tallow derivatives,
4. Status of cattle hide, and
5. Testing method cited for determining the level of insoluble impurities in tallow.

We are making these amendments to the interim final rule in part in response to comments indicating uncertainty regarding the status of certain products under the interim final rule and new information regarding removal of the distal ileum.

II. Amendments and Clarifications to the Interim Final Rule

A. Prohibition on the Use of Small Intestine From All Cattle

In the interim final rule of July 14, 2004, FDA prohibited the use of the entire small intestine in human food and cosmetics, even though the agency (at the time the interim final rule was issued) only considered, and currently only considers, the distal ileum portion of the small intestine to be an SRM. As stated in the preamble to the interim final rule, FDA prohibited the use of the entire small intestine because at the time we believed: (1) It would be difficult to distinguish one end of the small intestine from the other once it had been removed from the animal; (2) there was a lack of international agreement on how much of the small intestine should be removed to ensure that the distal ileum is separated from the remainder of the intestine; and (3) given the lack of international consensus on the issue, a manufacturer or processor would not be able to document that the distal ileum was adequately removed (69 FR 42256 at 42259). We requested comments addressing our reasons for prohibiting use of the entire small intestine and solicited specific information on whether processors may be able to effectively remove just the distal ileum.

1. Comments Received

In response to the interim final rule, FDA received comments from beef processors, the natural casing industry, the beef by-product industry, and importers and exporters of natural casings and beef by-products that requested that the agency amend its prohibited cattle materials rule to prohibit only the distal ileum portion of the small intestine for human food and cosmetics, rather than the entire small intestine. As stated in the comments, infectivity has only been confirmed in the distal ileum of the small intestine of cattle infected with BSE under experimental conditions, and the technology exists to effectively remove the distal ileum portion from the rest of the small intestine.

Comments also described, in detail, examples of verifiable procedures for the effective removal of the distal ileum portion of the small intestine, which is made up of three sections: The duodenum, the jejunum, and the ileum. One procedure described in the comments begins with the removal of the small intestine from the abomasum. Under this procedure, the small intestine is separated from the caecum at the ileocecal orifice, and the ileum is separated from the jejunum at the flange. According to the comments, the resulting segment that contains the distal ileum would measure 36 to 72 inches in length depending on the age and size of the animal.

Another procedure described in the comments also begins with removal of the small intestine from the abomasum, except that under this procedure the small intestine remains attached to the caecum. The separation of the non-ileum sections of the small intestine from the ileum is made at a point 36 to 80 inches from the caecum, leaving the entire ileum of the small intestine attached to the caecum. According to the comments, leaving the ileum attached to the caecum at this initial stage provides an easily verifiable point of reference for on-line inspectors. The next step in this procedure is to separate the 36 to 80 inch portion of the intestine that contains the ileum from the caecum at the ileocecal orifice, leaving the caecum and the small intestine for edible use.

Another comment noted that, prior to December 2003, Japan accepted importation of beef casings from the United States on the basis of U.S. government certified removal of the distal ileum from the small intestine. The procedure required the removal of at least 80 inches of the small intestine, measured from the junction of the ileum and the caecum, to ensure removal of the distal ileum.

Several comments indicated that, because of the distinct shape of the distal ileum of cattle, it is easy to verify the effective removal of this portion of the small intestine. Furthermore, comments from the natural casing industry stated that, because of the distal ileum's physical properties, particularly the absence of a curve and an irregular thick surface, the distal ileum is not useable as a natural casing for sausage products. Thus, these comments noted, many slaughter establishments in the United States and Canada have a policy of removing the distal ileum from all cattle at the time of slaughter. Furthermore, as stated by the comments, slaughter establishments in Brazil, Argentina, and Uruguay, the three countries that are the major exporters of natural casings to the United States, have all been able to certify the removal of the distal ileum using achievable standards when requested to do so by their U.S. customers.

In addition to comments requesting that only the distal ileum portion of the small intestine be prohibited from use in human food and cosmetics, we received comments stating that the entire small intestine or both the small and large intestines should be considered SRMs. Comments noted that the European Union (EU) identifies both the small and large intestine as specified risk material and prohibits their use in food. As stated in comments, this was done in the EU because BSE infection is associated with absorption of the BSE agent from contaminated feed and because it is not possible to prevent slaughterhouse contamination of other intestinal areas with matter from the ileum. Comments also cited a study showing that the myenteric plexus of the distal ileum was positive when immunostained in naturally infected and experimentally infected cattle. The comments noted that, because the myenteric plexus runs throughout the intestine, the possibility of infectivity in other sections of the intestine cannot be discounted. Comments also noted that the International Review Team (IRT), appointed to review BSE prevention measures in the United States after the discovery of the BSE-positive cow in Washington State, recommended that the SRM ban be amended to include the entire small and large intestines.

2. Response to Comments

After considering the comments submitted on the removal of the distal ileum, FDA has concluded that processors have the technology to effectively remove the distal ileum portion from the rest of the small intestine.

FDA believes that procedures to ensure effective removal of the distal ileum require that at least 80 inches of

the uncoiled and trimmed small intestine, as measured from the caeco-colic junction and progressing proximally towards the jejunum, be removed. We believe that these procedures ensure removal of the entire distal ileum despite differences in length of the intestinal tract or its segments between breeds or among animals of different sizes of the same breed. An alternative removal procedure may be used if an establishment can demonstrate that it is equally effective in ensuring that the entire distal ileum is completely removed.

We do not agree with comments that stated that the entire small intestine or both the small and the large intestine should be designated as SRMs. Though the EU prohibits the entire intestine from use in food, the data that we are aware of indicating infectivity along the entire intestine is from other species, not from cattle infected with BSE or other transmissible spongiform encephalopathies (TSEs) (Refs. 1 to 6). Though the studies in other species represent the distribution of infectivity in those species, they may not represent the distribution of infectivity in cattle infected with BSE as evidenced by studies with bovine tissue.

In cattle, infectivity has been found in the distal ileum in tissue bioassay from cattle experimentally given BSE (Ref. 7; see discussion in sections I. E and F of the interim final rule). In cattle experimentally infected with BSE, positive Peyer's patches were found by immunohistochemistry only in the distal ileum, and in cattle with naturally occurring and experimental BSE, positive myenteric plexus neurons were found only in the distal ileum (Ref. 8). The duodenum of cattle experimentally given BSE has not demonstrated infectivity when tested by mouse bioassay and has been negative for the presence of abnormal prions when examined by immunohistochemistry during all stages in the pathgenesis of the disease (Refs. 8 and 9). Few samples of jejunum have been tested, but those that have been tested were negative for the presence of abnormal prions when examined by immunohistochemistry (Ref. 8). In a bioassay of tissues from cattle with naturally-occuring BSE, no infectivity was found in the splanchnic nerve, rumen, omasum, abomasum, proximal small intestine, proximal colon, distal colon, and rectum, or even in the distal small intestine (Ref. 9).

The study by Terry and others (Ref. 8) indicated that the myenteric plexus of the distal ileum contained some abnormal prion protein in neurons. This tissue extends throughout the small intestine, so we cannot completely eliminate the possibility that infectivity might exist in the jejunum or the duodenum. However, that same study found no evidence of abnormal prion protein in the sections of the duodenum and the jejunum examined. Therefore, it is likely that, if any infectivity is present, it is at levels too low to present a public health risk. We realize that the studies on tissue infectivity have limitations, but we are not aware of evidence that intestine other than the distal ileum harbors infectivity in cattle with BSE. If we become aware of data indicating that other portions of the small intestine or the large intestine in cattle harbor infectivity, we will take action appropriate to the public health risk presented by the tissues.

We also do not agree that cross contamination of other parts of the intestine with infectivity in the distal ileum is unavoidable in the slaughterhouse. Comments provided several methods by which the distal ileum can be consistently and effectively removed from the rest of the small intestine without cross contamination during slaughter. We agree that, if these methods are properly implemented, cross contamination can be avoided.

Finally, we do not agree that we should require that the entire intestine of all cattle be designated an SRM because the IRT recommended it. As stated previously in this document, the agency does not find that there is sufficient evidence to support designating the entire intestine as an SRM.

Therefore, we are amending §§ 189.5(a)(1) and 700.27(a)(1) to reflect that small intestine is a prohibited cattle material unless it meets the provisions of new §§ 189.5(b)(2) and 700.27(b)(2). New §§ 189.5(b)(2) and 700.27(b)(2) state that small intestine is not considered prohibited cattle material if the distal ileum is removed by a procedure that verifiably 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.

These amendments to FDA's interim final rule are consistent with amendments that USDA made to its interim final rule regarding use of small intestine appearing elsewhere in this issue of the **Federal Register**. FDA regulates stripped and cleaned casings derived from bovine small intestine, and USDA's FSIS regulates unprocessed bovine small intestine and ''meat food'' products made with beef casings. It is important to note that natural beef casings and other FDA regulated products derived from small intestine are also subject to FSIS requirements when used in FSIS regulated products. Specifically, FSIS will not permit natural casings derived from beef small intestine to be used in meat food products unless the casings are derived from cattle that have been inspected and passed in a U.S. official establishment or in a certified foreign establishment.

B. Status of Milk and Milk Products

The interim final rule provides that no human food or cosmetics shall be manufactured from, processed with or otherwise contain, prohibited cattle materials. Prohibited cattle materials include material from cattle not inspected and passed for human consumption.

1. Comments Received

Several comments noted that milk and milk products could be viewed as products that are not inspected and passed because milk is obtained from live animals that do not undergo the same inspection as cattle during slaughter. These comments noted that milk and milk products are internationally recognized to present a negligible risk of transmitting the agent that causes BSE and asked that we clarify the status of milk and milk products under the interim final rule.

2. Response to Comments

The interim final rule applies to materials from cattle slaughtered on or after the effective date and was not meant to apply to milk and milk products, which come from live cattle. Therefore, we are amending §§ 189.5(a)(1) and 700.27(a)(1) to clarify that milk and milk products are not included in the definition of ''prohibited cattle materials.''

C. Clarification of the Classification of Tallow Derivatives

The interim final rule defines tallow and tallow derivatives and states that prohibited cattle materials do not include tallow that contains no more than 0.15 percent hexane-insoluble impurities and tallow derivatives.

1. Comments Received

Several comments requested that we clarify whether the tallow used as starting material for the tallow derivatives has to contain no more than 0.15 percent insoluble impurities in order for the tallow derivatives not to be included in the definition of ''prohibited cattle materials.''

2. Response to Comments

The exemption of tallow derivatives from the definition of ''prohibited cattle materials'' does not depend on the source tallow for the derivatives. For the reasons discussed in the preamble to the interim final rule, tallow derivatives present a negligible risk of transmitting the agent that causes BSE regardless of the source tallow. Therefore, all tallow derivatives are exempt from the ban on the use of prohibited cattle materials in human food and cosmetics.

D. Status of Human Food and Cosmetics Derived From Cattle Hide

The interim final rule provides that no human food or cosmetics shall be manufactured from, processed with or otherwise contain, prohibited cattle materials. Prohibited cattle materials include products that have not been inspected and passed for human consumption. Cattle hides, which are used as source material for collagen and collagen casings, receive antemortem but not postmortem inspection in most slaughter operations.

1. Comments Received

Several comments stated that the commenters did not believe that FDA meant to designate all cattle hide and products derived from hide as prohibited cattle material because they do not undergo postmortem inspection. These comments also pointed out that antemortem inspection is when BSE might be detected from the behavior or appearance of the animal, while postmortem inspection is more useful for detecting cross contamination among parts of the carcass. Comments indicated that risk of cross contamination by other carcass parts is not relevant for the hide because it is removed at the beginning of the slaughter process. In addition, comments noted that cattle hide is internationally recognized to be a tissue with a negligible risk of transmitting the agent that causes BSE, and the World Organization for Animal Health (OIE) recommends that it be freely traded regardless of the BSE risk status of the exporting countries.

2. Response to Comments

We agree with these comments. It was not our intention to designate all products derived from cattle hide as prohibited cattle materials for use in human food and cosmetics. We also recognize that cattle hide has been determined to be a tissue with negligible risk of transmitting the agent that causes BSE and that the OIE recommends that it be freely traded regardless of the BSE risk status of the exporting countries. Therefore, we are exempting hides from the provisions of the interim final rule and are amending §§189.5(a)(1) and 700.27(a)(1) to clarify that hides and hide-derived products are not included in the definitions of ''prohibited cattle materials.'' Though we are exempting hides from the provisions of the interim final rule, manufacturers and processors must take precautions to avoid cross contamination of hides and other nonprohibited cattle material with prohibited cattle material during slaughter and processing. If hides are cross contaminated with prohibited cattle material, they will be considered adulterated.

E. Method for Determining the Level of Insoluble Impurities in Tallow

Under the interim final rule (§§ 189.5(a)(6) and 700.27(a)(6)), any raw materials may be used as the starting material for tallow production as long as the resulting tallow contains no more than 0.15 percent hexane insoluble impurities. The interim final rule requires that the method for ''hexane-insoluble matter'' described in the 5th edition of the Food Chemicals Codex (FCC) be used to measure hexane-insoluble impurities in tallow. The interim final rule also states that an alternative method may be used if it is equivalent to the FCC method.

1. Comments Received

We received several comments requesting that we specify a different method for measuring insoluble impurities in tallow. Comments stated that the domestic tallow industry primarily uses a method of the American Oil Chemists' Society (AOCS) to measure insoluble impurities. In comparison to the FCC method, comments stated that the AOCS method is less expensive, requires less solvent and has lower solvent disposal costs, and does not require specialized equipment or supplies. These comments requested that FDA approve the AOCS method for measuring insoluble impurities.

2. Response to Comments

FDA agrees that the FCC method is more expensive, uses more solvent, and requires more specialized equipment than other methods currently used by industry. In response to comments and the information we obtained about the various methods, we are amending the interim final rule to cite the method for measuring insoluble impurities of the AOCS (''Insoluble Impurities,'' AOCS Official Method Ca 3a-46) or a method equivalent to it in accuracy, precision and sensitivity. The AOCS method is currently used by the domestic tallow industry, uses updated equipment, is less expensive to implement, and may be more sensitive than the FCC method.

Reference to the AOCS method in the amended interim final rule does not exclude use of the FCC method we cited in the interim final rule. Any testing method may be used that is equivalent to the AOCS method. Those wishing to use an alternate test are responsible for determining that it is equivalent to the AOCS method cited in the interim final rule as amended here; it is not necessary that FDA approve the use of an alternate test.

III. Summary of Amendments to the Interim Final Rule

We are amending §§ 189.5(a)(1) and 700.27(a)(1) to reflect that small intestine is a prohibited cattle material unless it meets the provisions of new §§ 189.5(b)(2) and 700.27(b)(2). New §§ 189.5(b)(2) and 700.27(b)(2) state that 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.

We are amending §§ 189.5(a)(1) and 700.27(a)(1) to specify that milk and milk products and hides and hide-derived products are not prohibited cattle materials.

Finally, we are amending §§ 189.5(a)(6) and 700.27(a)(6) to indicate that tallow, if it is sourced from unknown materials, must contain not more than 0.15 percent insoluble impurities as determined by the method ''Insoluble Impurities'' (AOCS Official Method Ca 3a-46), AOCS, or another method equivalent in accuracy, precision, and sensitivity to AOCS Official Method Ca 3a-46.

IV. Effective Date and Opportunity for Public Comment

FDA provided the public with an opportunity to comment on the issues raised by the interim final rule and addressed in this document. These amendments to the interim final rule are in response to some of those comments. These amendments to the interim final rule are effective October 7, 2005. FDA invites public comment on these amendments to the interim final rule. The comment period will be 60 days. The agency will consider modifications to these amendments to the interim final rule based on comments made during

the comment period. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding these amendments to the interim final rule. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

FDA will address other comments received in response to the interim final rule and comments received in response to this amendment in further rulemaking.

V. Executive Order 12866 and Regulatory Flexibility Act

FDA has examined the economic implications of this amendment to the interim final rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: Having an annual effect on the economy of $100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. FDA has determined that this amendment to the interim final rule is not an economically significant regulatory action.

FDA has examined the economic implications of this amendment to the interim final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. FDA has determined that this amendment to the interim final rule does not have a significant economic impact on a substantial number of small entities.

Bovine Small Intestine

The effect of amending the interim final rule will be that FDA regulated human food and cosmetics may be manufactured from, processed with, or otherwise contain small intestine if the distal ileum is effectively removed. FDA regulates stripped and cleaned casings derived from bovine small intestine, and USDA's FSIS regulates unprocessed bovine small intestine and ''meat food'' products made with beef casings. Very few, if any, FDA regulated foods use beef intestines or beef casings as an ingredient. Therefore, the impact on FDA regulated food industries as a result of this amendment to the final rule is expected to be small. In the economic analysis of the interim final rule, FDA did not estimate any opportunity costs for cattle slaughterers or manufacturers that used beef small intestines and beef natural casings in their products because the small intestine had already been banned as human food by the FSIS interim final rule (69 FR 1862, January 12, 2004).

USDA's FSIS is amending its interim final rule to allow the use of bovine small intestine, without the distal ileum, in USDA regulated products. FDA's amendment will benefit those FSIS regulated manufacturers who use beef casings; FDA's amendment again allows this bovine material potentially to be used in FSIS regulated products. See the FSIS interim final rule (69 FR 1862; January 12, 2004) and accompanying analysis for the cost savings associated with the renewed use of bovine small intestine in human foods products.

Tallow

FDA is amending the interim final rule to cite the AOCS method for measuring insoluble impurities in tallow. The domestic tallow industry primarily uses the AOCS method to measure insoluble impurities in tallow, so this change to the rule will reduce the burden of having to switch to a new measurement standard for many of the domestic tallow manufacturers. In comparison to the FCC method cited by the interim final rule, commenters stated that the AOCS method is less expensive than the FCC method. Tallow producers do not have to use the AOCS method if they use another method that is equivalent to the AOCS method in accuracy, precision, and sensitivity. Tallow producers using nonAOCS methods that can be validated will likely not switch methods and will only bear the cost burden of validating that their method is equivalent to the AOCS method. Tallow producers, who do not currently use the AOCS method but decide to switch to the method as a result of this amendment to the interim final rule, will pay a $50 fee to obtain the AOCS copyrighted method.

VI. 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. (FDA has verified the Web site addresses, but we are not responsible for subsequent changes to the nonFDA Web sites after this document publishes in the **Federal Register**.)

1. Jeffrey, M., S. Ryder, S. Martin, et al., ''Oral Inoculation of Sheep With the Agent of Bovine Spongiform Encephalopathy (BSE). 1. Onset and Distribution of Disease-Specific PrP Accumulation in Brain and Viscera,'' *Journal of Comparative Pathology*, 124: 280–289, 2001.

2. Bons, N., S. Lehmann, N. Nishida, et al., ''BSE Infection of the Small Short-Lived Primate Microcebus Murinus,'' *Comptes Rendus Biologies*, 325: 67–74, 2002.

3. Herzog, C., N. Sales, N. Etchegaray, et al., ''Tissue Distribution of Bovine Spongiform Encephalopathy Agent in Primate After Intravenous or Oral Infection,'' *Lancet*, 363: 422–428, 2004.

4. Jeffrey, M., I. Begara-McGorum, S. Clark, et al., ''Occurrence and Distribution of Infection-Specific PrP in Tissues of Clinical Scrapie Cases and Cull Sheep From Scrapie-Affected Farms in Shetland,'' *Journal of Comparative Pathology*, 127: 264–273, 2002.

5. Press, C. McL., R. Heggebo, A. Espenes, ''Involvement of Gut-Associated Lymphoid Tissue of Ruminants in the Spread of Transmissible Spongiform Encephalopathies,'' *Advanced Drug Delivery Reviews*, 56: 885–899, 2004.

6. Heggebo, R., C. McL. Press, G. Gunnes, ''Distribution and Accumulation of PrP in Gut-Associated and Peripheral Lymphoid Tissue of Scrapie-Affected Suffolk Sheep,'' *Journal of General Virology*, 83: 479–489, 2002.

7. Wells, G. A. H., M. Dawson, S. A. C. Hawkins, et al., ''Infectivity in the Ileum of Cattle Challenged Orally With Bovine Spongiform Encephalopathy,'' *Veterinary Record*, 135: 40–41, 1994.

8. Terry, L. A., S. Marsh, 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*, 152: 387–392, 2003.

9. Scientific Steering Committee, European Commission, ''Update on the Opinion of TSE Infectivity Distribution in Ruminant Tissues: Initially Adopted by the Scientific Steering Committee at its Meeting of January 10–11, 2002, and Amended at its Meeting of November 7–8, 2002, Following the Submission of a Risk Assessment by the German Federal Ministry of Consumer Protection, Food and Agriculture and New Scientific Evidence Regarding BSE Infectivity Distribution in Tonsils,'' accessed online at *http://europa.eu.int/comm/food/fs/bse/scientific_advice08_en.html*.

List of Subjects

21 CFR Part 189

Food additives, Food packaging, Incorporation by reference.

21 CFR Part 700

Cosmetics, Packaging and containers, Incorporation by reference.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 189 and 700 are amended as follows:

PART 189—SUBSTANCES PROHIBITED FROM USE IN HUMAN FOOD

■ 1. The authority citation for 21 CFR part 189 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 371.

■ 2. Part 189 is amended by revising § 189.5 to read as follows:

Subpart B—Prohibited Cattle Materials

Sec.
§ 189.5 Prohibited cattle materials.

Subpart B—Prohibited Cattle Materials

§ 189.5 Prohibited cattle materials.

(a) *Definitions.* The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) apply to such terms when used in this part. The following definitions also apply:

(1) *Prohibited cattle materials* means specified risk materials, small intestine of all cattle except as provided in paragraph (b)(2) of this section, material from nonambulatory disabled cattle, material from cattle not inspected and passed, or mechanically separated (MS)(Beef). Prohibited cattle materials 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 meets 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 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*.

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

(b) *Requirements.*

(1) No human food 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 human food that is manufactured from, processed with, or otherwise contains, cattle material must make existing records relevant to compliance with this section available to FDA for inspection and copying.

(d) *Adulteration.*

(1) Failure of a manufacturer or processor to operate in compliance with the requirements of paragraphs (b) or (c) of this section renders human food adulterated under section 402(a)(4) of the act.

(2) Human food manufactured from, processed with, or otherwise containing, prohibited cattle materials is unfit for human food and deemed adulterated under section 402(a)(3) of the act.

(3) *Food additive status.* Prohibited cattle materials for use in human food are food additives subject to section 409 of the act, except when used as dietary ingredients in dietary supplements. The use or intended use of any prohibited cattle material in human food causes the material and the food to be adulterated under section 402(a)(2)(C) of the act if the prohibited cattle material is a food additive, unless it is the subject of a food additive regulation or of an investigational exemption for a food additive under § 170.17 of this chapter.

PART 700—GENERAL

■ 3. The authority citation for 21 CFR part 700 continues to read as follows:

Authority: 21 U. S. C. 321, 331, 352, 355, 361, 362, 371, 374.

■ 4. Part 700 is amended by revising § 700.27 to read as follows:

§ 700.27 Use of prohibited cattle materials in cosmetic products.

(a) *Definitions.* The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) apply to such terms when used in this part. The following definitions also apply:

(1) *Prohibited cattle materials means* specified risk materials, small intestine of all cattle except as provided in paragraph (b)(2) of this section, material from nonambulatory disabled cattle, material from cattle not inspected and passed, or Mechanically Separated (MS)(Beef). Prohibited cattle materials

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*.

(7) *Tallow derivative* means any chemical obtained through initial hydrolysis, saponification, or trans-esterification of tallow; chemical conversion of material obtained by hydrolysis, saponification, or trans-esterification 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.

[FR Doc. 05–17693 Filed 9–6–05; 8:45 am]

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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.

[FR Doc. 05–17645 Filed 9–6–05; 8:45 am]

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