change in service, ERG estimated a transportation cost increase of 40 to 80 percent for the 141 rendering facilities that process mammalian protein currently prohibited in ruminant feed. Although most of these renderers do not handle both mammalian protein currently prohibited in ruminant feed and ingredients for feeds for ruminants, they rely on transportation services (most likely contractor services) that transport both materials, and thus would not be in compliance. These transportation cost increases are projected to total $8 to $16 million per year for the rendering industry.

Feed mills would also be expected to incur transportation cost increases due to the prohibition under this option on backhauling ruminant feeds in trucks that are used to deliver feeds with mammalian proteins currently prohibited in ruminant feed. Since backhauling does not occur as often in the delivery of feed due to shorter average distances between feed mills and animal producers than from renderers to feed mills, ERG predicted the transportation cost increases at 25 to 50 percent for feed mills. Based on ERG's calculation of the quantity of feed that would be affected by the proposed rule (4.5 million tons) and the average transportation cost per ton of feed ($12.66), total transportation cost increases for feed mills were estimated to range from $14.2 to $28.4 million per year. These costs would include the amortized cost of capital equipment such as additional trucks, as well as incremental operating and maintenance costs. These costs would be incurred by about 200 feed mills. Again, this number is larger than the number of mills that handle both mammalian proteins currently prohibited in ruminant feed and ruminant feeds due to the additional number of mills that would rely on contract feed haulers that handle both materials. ERG acknowledges uncertainty in these estimates due to possible changes in mill dedication patterns, the analysis of which would have required additional geographic distribution data on feed mills and feed types.

If CMPAFs are banned from use in all animal feeds as proposed in this rule, the agency believes that a provision requiring dedicated facilities or equipment for those handling mammalian proteins currently prohibited in ruminant feed and preparing ruminant feeds would not be necessary because this proposed rule is expected to reduce the number of ID_{50}s available for use in animal feeds by about 90 percent. Requiring separate facilities or equipment for mammalian proteins currently prohibited in ruminant feed and ruminant feeds would not be expected to significantly reduce the risk of feeding prohibited proteins to ruminants, because nearly all of the potentially BSE infective tissues would be unavailable for use in feeds for any animals because of the CMPAF prohibition. Therefore, the risk is minimal that the BSE agent would be present even if cross-contamination occurs between mammalian protein intended for non-ruminant feed and ruminant feeds. The agency requests comment and data on the need for a requirement for dedicated facilities/equipment for those facilities that handle both mammalian proteins currently prohibited in ruminant feed and ruminant feed when a CMPAF ban also exists.

b. *Poultry litter prohibition.* The agency also considered a ban on poultry litter in ruminant feed. Poultry litter contains bedding material, spilled poultry feed, and manure, and is a waste by-product of poultry production. Because poultry feed may contain mammalian meat and bone meal currently prohibited in ruminant feed, there is a risk that cattle fed poultry litter containing spilled poultry feed may be exposed to prohibited meat and bone meal through that spilled poultry feed.

This alternative would ban the use of poultry litter in all ruminant feed. Its costs would be comprised of both substitution costs for the replacement materials needed to provide an equivalent nutritional value, and disposal costs if the poultry litter cannot be used as an alternative product, such as fertilizer. The risk reduction would be the elimination of the possibility of the spread of BSE through the recycling of mammalian proteins currently prohibited in ruminant feed back into cattle feed through poultry litter including the spilled poultry feed containing prohibited mammalian proteins.

A preliminary risk assessment of poultry litter submitted to the agency by an industry member predicted that in its worst-case scenario, under the current ruminant feed ban rule, a cow would need to eat 70.1 tons of litter to be exposed to 1 ID_{50} (Ref. 35). FDA modified some of the assumptions used in this risk assessment and predicted what would happen if there was no mixing during the cleanout process so that the spilled feed remained concentrated in a small portion of the bedding. Under this scenario, a ruminant fed only contaminated litter from under the poultry feeders must consume 3.4 tons to consume 1 ID_{50}. This tonnage is still beyond the volume a stocker steer would realistically consume under normal circumstances due to its relatively short life. Similarly, dairy cows would also not be expected to consume this amount since poultry litter is not generally used in feed for lactating dairy cows. Because it appears to pose only a small baseline risk of BSE for ruminants, FDA currently believes that banning poultry litter from ruminant rations would have little or no affect on the human risk while increasing the environmental risks of its alternative disposal methods. FDA requests comments on this issue.

Most poultry litter is not used as cattle feed. As an organic source of nutrients for plants, it has been applied to farmland for years. This practice, however, raised environmental concerns that excess nitrogen and phosphorus could leach from the litter and contaminate waterways. Since rumen microbes can efficiently metabolize poultry litter, feeding litter to cattle provides an alternative use to land application that benefits both poultry growers and cattle producers. Where poultry and cattle operations overlap, poultry growers are willing to sell litter at a price that exceeds the value of any alternative use. Cattle producers obtain a feed ingredient for a lower price than the next best alternative ingredient in the ruminant ration. Banning the use of litter in ruminant feed will likely increase the price of rations for ruminant producers and decrease revenues for poultry producers. Moreover, if poultry producers must dispose of unwanted litter, their operating costs would increase.

To analyze the impact of the ban on poultry litter on ruminant producers, we calculated the per ton price of equivalent cattle rations with and without poultry litter. Based on feed ingredient prices in March 2004 and using equivalent cattle ration formulations recommended by University of Georgia, rations with 38 percent to 53 percent poultry litter average about $65 per ton (Ref. 36). Equivalent rations without poultry litter average about $80 per ton, or about $15 per ton more than the ration with poultry litter. The average cattle fed about 16.5 pounds of feed daily for 200 days consumes a total of 0.6 tons to 0.9 tons of litter, depending on the percentage of litter in the ration. This suggests that the cost of feed will increase by about $25 per head ($15 per ton x 200 days per head x 16.5 pounds per day/2,000 pounds per ton). The annual supply of poultry litter can potentially feed between 1.3 million (1.1 million tons of litter / 0.9 tons of litter

per cow) and 3.2 million cows (2 million tons of litter / 0.6 tons of litter per cow). Thus the total cost of feed could increase from $32 million ($24.75 per cow x 1.3 million cows) to $80 million ($24.75 per cow x 3.2 million cows).

Vertical integration in the poultry industry often results in contract growers' contractual responsibility for litter management. For many reasons, including regional distribution of poultry producers and costly transportation, commodity markets do not handle poultry litter. Some poultry producing states have taken the initiative to promote and develop an infrastructure for litter markets, including programs to match the producers and users of poultry litter; providing transportation subsidies, or encouraging informal "markets" where buyers and sellers can contact each other.

Alternative uses for poultry litter are being developed, but are not widely available currently. With technology developed in the United Kingdom, the nation's first poultry litter fired power plant is being constructed in Missouri. Research is underway to convert litter into activated carbons that can absorb environmental pollution.

In areas where cattle and poultry production overlap, banning poultry litter from ruminant feed may require that growers store litter, probably in deep stacking sheds, until alternative uses can be identified. If it is not possible to store litter, however, growers may need to dispose of surplus litter in landfills. To illustrate the cost of a worst-case scenario, disposal of the entire 1.1 million to 2 million tons of litter would range from $44 million to $160 million with disposal fees that range from $40 to $80 per ton.

Without alternative outlets for litter banned from ruminant feed, the total short-run costs might range from $76 million to $240 million. Contract growers and ruminant producers, many of whom are small entities, would incur these costs. Although the poultry litter alternative has not been included in the proposed rule, the agency requests comment on the need for a poultry litter ban in ruminant feed when a CMPAF ban in all animal feed also exists.

c. *Blood and blood products prohibition.* We also considered an alternative that would have prohibited the use of blood and blood products in ruminant feed. We did not include this option in this proposed rule because we could not at this time show any BSE risk reduction as a result of such a prohibition, and these products have beneficial effects in ruminant feed. This option, if adopted, would result in one-time direct costs of about $7 million (annualized at $990,000 over 10 years at 7 percent) for relabeling, reformulation and reregistration, as well as additional revenue losses for the product manufacturers.

ERG identified and profiled the various blood and blood products used in animal nutrition. These products include plasma-based therapeutics and feed additives, premium blood-based feed additives and commodity blood meal. The prohibition of blood and blood products would result in some additional administrative costs to feed mills. It would require some mills to reformulate the rations in feeds. Relabeling efforts would also be required for some feeds, depending on whether the current label identifies specific animal proteins or identifies proteins under the broader term "animal protein products." Additionally, some of these feeds would need to be reregistered with state agencies due to their new labeling, resulting in additional administrative cost to the mills.

ERG prepared cost estimates for each of these activities based on FDA database information on feed ban inspections, data from industry-sponsored reports, an industry journal, and Bureau of Labor Statistics data. ERG estimated that about 2,300 feed mills offer some type of blood-meal containing feeds, and that these mills have, on average, about 44 feed mixes that would require reformulation due to their containing blood meal or another ruminant protein that would no longer be offered due to a dedicated facilities/equipment requirement. ERG prepared this estimate assuming that both a blood product prohibition and a dedicated facility/equipment requirement would be proposed. Therefore, to the extent that the estimated 44 feed mixes represent not those containing blood products but rather another ruminant protein that would no longer be available if a dedicated facilities/equipment requirement had been created, these costs will be overestimated. Based on the various labor rates for mill employees, ERG estimated that reformulation efforts would result in a one-time total cost of $2.85 million. Relabeling costs, including both printing plate preparation and additional labor hours, are estimated to result in a one-time cost of $2.77 million. Reregistration costs are projected to add another one-time cost of $1.34 million. In total, these efforts would result in a one-time cost of $6.96 million (average one-time costs per affected mill would be about $3,000). Annualized over 10 years at a 7-percent discount rate, this equates to $990,000 per year (see table 4 of this document).

TABLE 4.—ADMINISTRATIVE COSTS

Cost Element	One-Time Costs (Thousands)	Annualized Costs[1] (Thousands)
Reformulation	$2,853	$406
Relabeling	$2,771	$395
Reregistration	$1,340	$190
Total Costs	$6,963	$990

[1]Over 10 years at a 7 percent discount rate.

Along with the compliance costs mentioned previously, this option would also result in the loss in value of the blood products themselves. ERG's discussions with producers of plasma-based products for therapeutic use led to the following conclusion. Most of these products would not find an acceptable alternative market, or would do so only at a steep price discount, due to their reduced efficacy when used in animals other than cattle. Although ERG projected future market volumes based on industry contacts, current sales of these products are unavailable. Plasma-based feed additives and premium blood-based feed additives are not as species-specific and could be shifted to use in non-ruminant markets assuming a smaller decrease in price than would likely occur with the therapeutic

products. These products, which could be shifted to use in non-ruminant markets, may also incur higher transportation costs because fewer mills would be expected to accept any mammalian proteins currently prohibited in ruminant feed, that is if the dedicated facilities/equipment was also required. Commodity ruminant blood meal, valued at about $41 million in 2003, would also be expected to lose value due to this option. Porcine based blood meal would be expected to increase in value. These losses have not been projected.

At this time, the agency does not have evidence that BSE is transmitted to cattle via blood or blood products. Therefore, the agency has not proposed that these products be banned from use in ruminant feeds in this proposal. The agency requests further comment and scientific information on the need to prohibit the use of blood and blood products in ruminant feed.

d. *Plate waste prohibition.* This alternative would have eliminated the current exemption of inspected meat products which have been cooked and offered for human food, and further heat processed for feed (commonly referred to as plate waste but also including used cellulosic food casings) from the current definition of protein derived from mammalian tissues. It would ban plate waste from use in ruminant feed.

As previously mentioned in the preamble to this proposed rule, the agency requested comment on questions related to the use of plate waste in ruminant feeds in the 2002 ANPRM. These questions focused on the extent of plate waste use in ruminant feeds, the composition of plate waste and its sources, plate waste processing techniques prior to its inclusion in feed, and the adverse and positive impacts for excluding plate waste from feed. Although the agency received many comments to the 2002 ANPRM, they did not include estimates of usage or regulatory impacts that were specific enough to form a foundation for a cost analysis of this option. One comment stated that the amount of plate waste used in ruminant feed was low. Another comment mentioned that substantial tonnages were used in ruminant feed in at least one state. A third comment stated that plate wastes from correctional facilities in another state were used in ruminant feed. No additional data was included to support these statements about the extent of plate waste use in ruminant feed. One comment stated that there were six processors of plate waste in the United States, but did not list these processors or offer any estimate of the use or value of processed plate waste in ruminant feed.

We tried to collect more information on the use of plate waste in ruminant feed and any expected impacts from its ban in ruminant feed, by contacting all those who commented to the ANPRM about plate wastes. The comment that mentioned the use of plate waste from correctional facilities offered additional anecdotal data about this practice in one state, stating this practice was common in areas that had cattle or hog farms located near correctional facilities. It is likely, though, that because most or all of this plate waste is not currently further heat processed for feed, it would not be exempt from the current feed ban as defined in the 1997 ruminant feed final rule. No additional data on actual volumes of plate waste was offered. Another state agriculture agency that responded to the ANPRM, when contacted for further information, also stated that very little, if any, plate waste was further heat processed and used in ruminant feeds. Further, earlier estimates of significant tonnages of plate waste being used in feeds could not be verified by this agency through its investigators in the field. The other comments did not respond to our attempts at further contact.

We also requested the assistance of agency personnel with knowledge of the ruminant feed industry in estimating the extent of use of plate waste in ruminant feeds. Although these agency sources acknowledge that the practice exists, we do not have any estimate of its prevalence on a national level. According to these agency sources, since plate waste (including used cellulosic food casings) is expected to have a relatively low nutritional value when used as a supplement in ruminant feeds, it would not be used in ruminant feed as a general rule. While the agency acknowledges that some plate waste is currently used in ruminant feeds, it cannot offer an estimate of this plate waste volume. The agency acknowledges there would be incremental disposal costs and alternative feed costs, due to a ban on the use of plate wastes in ruminant feeds. However, the agency cannot reliably estimate these costs at this time.

The agency has concluded that this additional measure would be unnecessary given that measures already implemented by USDA and FDA to prohibit SRMs from human food effectively eliminate BSE infectivity from plate wastes. The agency requests further public comment on the extent of plate waste use in ruminant feeds and the costs such a prohibition would impose on any industry members.

e. *SRM prohibition.* A final alternative would prohibit the use of a more extensive list of cattle materials in any animal feed. These materials would include the following: (1) SRMs, (2) The small intestine of all cattle, (3) material from cattle not inspected and passed for human consumption (including nonambulatory disabled cattle), (4) tallow containing more than 0.15 percent insoluble impurities if derived from prohibited material, and (5) MS beef. SRMs would be defined as the skull, brain, eyes, spinal cord, trigeminal ganglia, 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 all cattle 30 months of age or older, plus the tonsils and distal ileum of all cattle regardless of age.

FDA stated in July 2004 that it was considering this alternative, and ERG completed a cost analysis of this option. It is available at the Division of Dockets Management (see ADDRESSES).

This alternative would require slaughterers to separate SRMs from slaughter cattle, and require renderers and firms that process dead, down, disabled, and diseased cattle (cattle not inspected and passed for human consumption) to separate all material from such animals from the remaining cattle offal produced for eventual use as animal feed. We estimate that the separation of these SRMs and material from cattle not inspected and passed for human consumption would require about $26.5 million in one-time capital costs (or $3.8 million annualized at 7 percent and $3.1 million annualized at 3 percent, over 10 years). We estimate that the annual cost of the additional labor to separate SRMs from other cattle offal is estimated to cost about $9.2 million annually. The analysis projected that SRMs, instead of being rendered for animal feed, would most likely be rendered for disposal, based on the large amount of banned material this option would generate. To the extent that some states would allow landfilling (another relatively low cost disposal option), this analysis may overestimate compliance costs. Although compliance costs for these activities would be borne initially by slaughterers, and are presented as such by ERG, a portion of the costs are likely to be passed through to cattle producers and consumers. Annual rendering costs, which would include the value of the MBM net of the value of the recovered tallow, would range from $24 million to $88 million at the low estimate of the number of cattle not inspected and passed for human consumption that are currently rendered

to $31 million to $117 million at the high estimate. Additional SRM transportation costs would be incurred to move SRMs and cattle not inspected and passed for human consumption from slaughterers to disposal renderers, and to move nonSRM offal a further distance to another renderer due to their current renderer becoming a for-disposal-only renderer. We estimate these to range from $22 million to $39 million at the low estimate of cattle not inspected and passed for human consumption that are rendered to $33 million—$58 million at the high estimate annually. Additionally, the estimated cost to dispose of the resulting MBM is estimated at $8 million—$16 million at the low estimate and $12 million -$24 million annually at the high estimate. Total annualized costs of the prohibition of SRM, cattle not inspected and passed for human consumption (as shown in table 4 of this document) are estimated to range from $76 million to $161 million at the low end of the estimates of cattle not inspected and passed for human consumption that are rendered. Using the high estimate, annualized costs would range from $102 million to $225 million. FDA expects MBM disposal costs to decrease in the future with the development of alternative markets for MBM of SRM-origin, but can offer no projections of these cost reductions.

These cost estimates assume the development of a rendering industry dedicated entirely to disposal. This industry would earn no fees from selling rendered material, but would instead charge slaughterers and cattle owners for the disposal of prohibited materials. Information submitted to the agency implies that some independent rendering establishments would be used as rendering for disposal, contingent upon a volume of SRM products that would make disposal rendering profitable. It may be possible that some geographic areas would be underserved by disposal renderers due to the lack of availability of SRMs and cattle not inspected and passed for human consumption, necessary to provide the service at a charge that is lower than the cattle producers' indirect cost of on-farm disposal of cattle not inspected and passed for human consumption. Neither FDA nor ERG has the geographic data on renderer locations and offal suppliers, or the financial data on individual renderers necessary to predict the number or geographic location of rendering establishments that will undertake SRM rendering for disposal. Further discussion of the implications for the development of a disposal rendering industry is available in the environmental assessment of this proposed rule. We request comments and data concerning the development of a rendering industry dedicated to rendering for disposal only of SRM and cattle not inspected and passed for human consumption.

ERG determined that the prohibition on the use of tallow derived from the list of cattle materials prohibited under this alternative option that contains more than 0.15 percent hexane-insoluble impurities would result in annualized costs estimated at $2. million. These costs consist of capital and operating costs for polishing centrifuges that would be needed by a small segment of independent renderers (further analysis of this provision led ERG to reduce the estimated cost, as it reported in its analysis of the proposed rule, to $1.78 million annually). The loss in market value of both MS beef and muscle tissue from cattle not inspected and passed for human consumption used in animal feeds is projected at about $75 million. FDA acknowledges that this last estimate is speculative because these sales cannot be distinguished from other renderer sales in U.S. Census data. FDA invites public comments and data on the impacts of the provisions that would prohibit all tallow derived from the prohibited materials that contains more than 0.15 percent insoluble impurities and all MS beef from use in animal feeds. Total costs of this alternative are estimated to range from $154.0 million to $242.6 million annually for the low estimate of cattle not inspected and passed for human consumption. Using the high estimate, total annualized costs are projected at $178 million to $302 million Table 5 of this document displays the costs associated with this alternative.

TABLE 5.—TOTAL COSTS ($ MILLIONS)[1]

Cost Item	One-Time Cost	Annual Costs	Annualized Costs
Capital Investments	$27	N/A	$4
Labor		$9	$9
Net Rendering Costs[2]		($25–$88) to ($31–$117)	($25–$88) to ($31–$117)
SRM Transportation		($22–$39) to ($33–$58)	($22–$39) to ($33–$58)
Disposal Costs		($10–$18) to ($17–$29)	($10–$18 to ($17–$29)
SRM Marking		($0.02–$0.15) to ($0.03–$0.23)	($0.02–$0.15) to ($0.03–$0.23)
Recordkeeping/Labeling		$0.05 to $0.06	$0.05 to $0.06
Feed Substitution		$6–$7	$6–$7
Subtotal—Codified SRM, Dead, Downer Ban		($72–$161) to ($96–$220)	($76–$165) to ($100–$224)
Tallow Restriction	$11	$1	$2
MS Beef Ban		$75	$75
SRM Alternative Total Costs			($153.0–$242) to ($178–$302)

[1] Low cost estimate ranges reflect lower estimate of cattle not inspected and passed for human consumption. High cost estimate range reflect high end of estimates of cattle not inspected and passed for human inspection.
[2] Has been reduced by the value of the tallow products recovered.

To assess the risk reduction from the SRM alternative in this proposed rule, we use two distinct approaches. In the first approach, we assume that the number of new BSE cases is proportional to the amount of all infectious material included in feed. Given this assumption, we can estimate the percentage reduction in risk as the percentage reduction in infectious material. A report by the Scientific Steering Committee of the European Union suggests that the tissues designated as SRM (brain, spinal cord, trigeminal ganglia, dorsal root ganglia, distal ileum, eyes) constitute at least 99.44 percent of the total infective load (Ref. 29). These tissues (SRMs) from cattle 30 months of age and older, the tonsils and distal ileum of all cattle, and all material from cattle not inspected and passed for human consumption, would be prohibited from use in any animal feed under this alternative. SRMs (except for tonsils and distal ileum which are prohibited regardless of age of cattle), when taken from cattle less than 30 months of age, would not be prohibited from use in all animal feed because the probability is very low that tissues from cattle of this age would contain BSE infectivity. FDA estimates, therefore, that banning SRMs from use in any animal feed would effectively remove about 99 percent of any remaining infectivity from possible spread through the feed system.

The second approach uses the Harvard-Tuskegee risk assessment model, making adjustments to the infectivity pathways for cattle and humans that would still be available even after the USDA interim final rules concerning SRMs in human food and *Advanced Meat Recovery (AMR)* systems became effective. FDA has updated the model to simulate the introduction of five infected cattle into the United States. The model was also updated to further reduction in the spread of BSE among cattle and reduction in human exposure to cattle oral ID_{50}s that would result from a ban on SRMs in animal feeds. The USDA rule, prohibiting the use of SRMs in human food as well as the FDA interim final rule prohibiting the use of SRMs in human food and cosmetics, may cause some offsetting increases in the amount of SRMs that enter non-ruminant feeds; the proposed SRM ban would address this increase in SRMs in animal feed. Under this second approach, we define risk reduction as the reduction in human exposure that would result from the ban on the use of SRM in any animal feed using the HCRA model. These results show that prohibiting the use of SRMs in all animal feed would effectively negate about 95 percent of the remaining risk of human exposure to cattle oral ID_{50}s. When considered as a complementary measure to the USDA and FDA SRM bans for human food, the estimate of overall human exposure reduction from those bans and the SRM alternative is more than 99 percent.

The model does not take into account any additional risk reduction from the restrictions on the use of tallow or MS beef in animal feeds. While we believe these additional restrictions would likely further reduce the risk to human health from BSE to a small degree, we cannot quantify this risk reduction.

Compared to the proposed rule, this alternative would impose an additional $171 million to $226 million in annual compliance costs. As discussed earlier, we believe that this proposed rule provides the appropriate level of protection against the spread of BSE in a cost-effective manner.

V. Paperwork Reduction Act

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). A description of these provisions is given below with an estimate of the annual recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on the following topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Substances prohibited from use in animal food or feed.

Description: We are proposing to amend our regulations to prohibit the use of certain cattle origin materials in the food or feed of all animals. These materials include the following: (1) The brains and spinal cords from cattle 30 months of age and older (2) the brains and spinal cords from cattle of any age not inspected and passed for human consumption, (3) the entire carcass of cattle not inspected and passed for human consumption if the brains and spinal cords were not removed, (4) MS beef that is derived from cattle from which prohibited materials were not previously removed; and (5) tallow that is derived from cattle materials prohibited in animal feed unless such tallow contains no more than 0.15 percent insoluble impurities. These measures will further strengthen existing safeguards designed to help prevent the spread of BSE in U.S. cattle.

Description of Respondents: Rendering facilities, Medicated feed manufacturers and distributors, livestock feeders.

TABLE 6.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeper	Total Annual Records	Hours per Recordkeeper	Total Hours	Operation and Maintenance Cost
589.2001(b)(2)(iv) and (b)(3)(i)	141	1	141	20	2,820	$47,940
Total					2,820	

The estimated recordkeeping burden is derived from agency resources and discussions with affected industry. The recordkeeping requirement in proposed § 589.2001(b)(2)(iv) will apply to the limited number of renderers who will handle prohibited bovine material. We estimate that no more than 50 rendering firms will be involved in the handling

of this material. Although we may consider the distribution records needed to comply with this proposed regulation "usual and customary" and thus not subject to PRA, we believe there will be burden associated with setting up a system to assure such records are sufficient to address the proposed recordkeeping requirement. Likewise, although we may consider the records necessary to comply with proposed § 589.2001(b)(3)(i) as "usual and customary" and not subject to PRA burden accounting, we are including a burden estimate to cover establishment of a system to assure existing receipt and manufacturing records adequately address this proposed requirement.

In compliance with the PRA (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to submit written comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB).

OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

VI. Environmental Impact

The agency has carefully considered the potential environmental impact of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. FDA's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Division of Dockets Management (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday.

VII. Federalism

We have analyzed this proposed rule in accordance with the principles in Executive Order 13132. We have determined that the proposed rule does not contain policies that have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we have tentatively concluded that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VIII. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments regarding this document. 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.

IX. 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 FDA is not responsible for any subsequent changes to the Web site after this document publishes in the Federal Register.

1. Kimberlin, R.H. and J.W. Wilesmith, "Bovine Spongiform Encephalopathy: Epidemiology, Low Dose Exposure, and Risks," *Annals of the New York Academy of Sciences*, 724: 210–220, 1994.

2. Collee, J.G. and R. Bradley, "BSE: A Decade on-Part I," *Lancet*, 349: 636–41, 1997.

3. Harvard Center for Risk Analysis, Harvard School of Public Health, and Center for Computational Epidemiology, College of Veterinary Medicine, Tuskegee University, "Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States," Harvard Center for Risk Analysis Internet Page (*http://www.hcra.harvard.edu/pdf/madcow_report.pdf*), 2001.

4. Harvard Center for Risk Analysis, Harvard School of Public Health, and Center for Computational Epidemiology, College of Veterinary Medicine, Tuskegee University, "Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States," Harvard Center for Risk Analysis Internet Page (*http://www.hcra.harvard.edu/pdf/madcow.pdf*), 2003.

5. Harvard Center for Risk Analysis, Harvard School of Public Health, "Evaluation of the Potential Spread of BSE in Cattle and Possible Human Exposure Following Introduction of Infectivity into the United States from Canada," accessed online at Harvard Center for Risk Analysis Internet Page *http://www.hcra.harvard.edu/pdf/canadian/Text_2003_09_05_-_with_refs.pdf*, 2003.

6. U.S. Department of Agriculture, Animal and Plant Health Inspection Service (USDA/APHIS), report of the epidemiological investigation, "A Case of Bovine Spongiform Encephalopathy (BSE) in the United States," March 2004, USDA/APHIS Internet Page (*http://www.aphis.usda.gov/lpa/issues/bse/BSE_fr_ban%20_ltr_enc_1.pdf*).

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8. The transcripts of the October 30, 2001, public hearing on BSE, are available at the Division of Dockets Management (refer to Docket No. 01N–0423). The transcripts may also be obtained online at FDA Internet Page (*http://www.fda.gov/ohrms/dockets/dockets/01N-0423/01n0423.htm*).

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List of Subjects in 21 CFR Part 589

Animal feeds, Animal foods, Food additives, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, the Food and Drug Administration, it is proposed that 21 CFR part 589 be amended to read as follows:

PART 589—SUBSTANCES PROHIBITED FROM USE IN ANIMAL FOOD OR FEED

1. The authority citation for 21 CFR part 589 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 348, 371.

2. Section 589.2000 is amended by revising paragraph (a)(1) and by adding paragraphs (c)(4) and (e)(3) to read as follows:

§ 589.2000 Animal proteins prohibited in ruminant feed.

(a) * * *

(1) *Protein derived from mammalian tissues* means any protein-containing portion of mammalian animals, excluding: Blood and blood products; gelatin; tallow containing no more than 0.15 percent insoluble impurities and tallow derivatives as specified in § 589.2001; inspected meat products which have been cooked and offered for human food and further heat processed for feed (such as plate waste and used cellulosic food casings); milk products (milk and milk proteins); and any product whose only mammalian protein consists entirely of porcine or equine protein.

* * * * *

(c) * * *

(4) Renderers shall comply with all applicable requirements under § 589.2001.

* * * * *

(e) * * *

(3) Renderers shall comply with all applicable requirements under § 589.2001.

* * * * *

3. Section 589.2001 is added to read as follows:

§ 589.2001 Cattle materials prohibited in animal food or feed.

(a) *Definitions*—(1) *Cattle materials prohibited in animal feed include:*

(i) The brains and spinal cords of cattle 30 months of age and older;

(ii) The brains and spinal cords of cattle not inspected and passed for human consumption as defined in paragraph (a)(2) of this section;

(iii) The entire carcass of cattle not inspected and passed for human consumption from which brains and spinal cords were not removed;

(iv) Mechanically separated beef as defined in paragraph (a)(3) of this section that is derived from materials specified in paragraphs (a)(1)(i), (a)(1)(ii), and (a)(1)(iii) of this section; and

(v) Tallow as defined in paragraph (a)(5) of this section that is derived from materials specified in paragraphs (a)(1)(i), (a)(1)(ii), and (a)(1)(iii) of this section. Cattle materials prohibited in animal feed do not include:

(A) Tallow derivatives as defined in paragraph (a)(6) of this section and;

(B) Tallow as defined in paragraph (a)(5) of this section that is derived from materials specified in paragraphs (a)(1)(i), (a)(1)(ii), and (a)(1)(iii) of this section and that contains no more than 0.15 percent insoluble impurities. Insoluble impurities must be measured by the method entitled "Insoluble Impurities" of the American Oil Chemists' Society (Official Method Ca 3a–46), or another method equivalent in accuracy, precision, and sensitivity to AOCS Official Method Ca 3a–46. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies of the method from the AOCS (*http://www.aocs.org*). 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.*

(2) *Cattle not inspected and passed for human consumption* means cattle of any age that were not inspected and passed for human consumption by the appropriate regulatory authority. This term includes nonambulatory disabled cattle. Nonambulatory disabled cattle are 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.

(3) *Mechanically separated beef* means a finely comminuted meat food product, resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle of cattle carcasses and parts of carcasses.

(4) *Renderer* means any firm or individual that processes slaughter byproducts, animals unfit for human consumption, or meat scraps. The term includes persons who collect such materials and subject them to minimal processing, or distribute them to firms other than renderers (as defined in this paragraph) whose intended use for the products may include animal feed, industrial use, or other uses. The term includes renderers that also blend animal protein products.

(5) *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.

(6) *Tallow derivative* means any product 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 animal feed or feed ingredient shall be manufactured from, processed with, or otherwise contain, cattle materials prohibited in animal feed as defined in paragraph (a)(1) of this section.

(2) Renderers that manufacture, process, blend, or distribute cattle materials prohibited in animal feed as defined in paragraph (a)(1) of this section, or products that contain or may contain cattle materials prohibited in animal feed, shall take the following measures to ensure that materials identified in paragraph (b)(1) of this section are not introduced into animal feed:

(i) Once cattle materials prohibited in animal feed have been separated from other cattle materials, provide for measures to avoid cross-contamination;

(A) Use separate equipment while handling cattle materials prohibited in animal feed; or

(B) Use separate containers that adequately prevent contact with animal feed, animal feed ingredients, or equipment surfaces;

(ii) Label the cattle materials prohibited in animal feed and products that contain or may contain cattle materials prohibited in animal feed in a conspicuous manner as follows: "Do not feed to animals";

(iii) Mark the cattle materials prohibited in animal feed and products that contain or may contain cattle materials prohibited in animal feed with an agent that can be readily detected on visual inspection; and

(iv) Establish and maintain records sufficient to track cattle materials prohibited in animal feed to ensure such material is not introduced into animal feed, and make the records available for inspection and copying by the Food and Drug Administration.

(3) Renderers that manufacture, process, blend, or distribute any cattle materials shall take the following measures to ensure that materials identified in paragraph (b)(1) of this section are not used in animal feed:

(i) Establish and maintain records sufficient to demonstrate that material rendered for use in animal feed was not manufactured from, processed with, or does not otherwise contain, cattle materials prohibited in animal feed, and make the copies available for inspection and copying by the Food and Drug Administration; and

(ii) Comply with all applicable requirements under § 589.2000 regarding animal proteins prohibited in ruminant feed.

(c) *Adulteration and misbranding.* (1) Failure of a renderer to comply with the requirements in paragraphs (b)(2)(i), (b)(2)(iii), (b)(2)(iv), or (b)(3)(i) of this section will render the animal feed or feed ingredients adulterated under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the act).

(2) Animal feed or feed ingredients that are not in compliance with paragraph (b)(1) of this section are adulterated under section 402(a)(2), 402(a)(3), or 402(a)(5) of the act.

(3) Animal feed or feed ingredients that are not in compliance with the labeling requirements of paragraph (b)(2)(ii) of this section are misbranded under section 403(a)(1) or 403(f) of the act.

(4) Failure of a renderer to comply with the requirements in paragraph (d) of this section will render the animal feed or feed ingredients adulterated under section 402(a)(4) of the act.

(d) *Inspection; records retention.* Records required to be made available for inspection and copying by the Food and Drug Administration, as required by this section, shall be kept for a minimum of 1 year.

Dated: July 26, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–20195 Filed 10–4–05; 1:00 pm]

BILLING CODE 4160–01–S