30 months of age or older and cattle not inspected and passed for human consumption regardless of age would require about $555,000 in one-time capital costs (or $79,000 annualized at 7 percent and $65,000 annualized at 3 percent, over 10 years) (see table 1 of this document). We estimate that the annual cost of the additional labor to separate these CMPAF from other cattle offal is estimated to cost about $597,000 annually. 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 along to cattle producers and consumers. For renderers, capital investments and labor for separation and segregation of CMPAF would range from about $1.88 million to $4.65 million annually.

Our analysis does not project a specific disposal route for CMPAF due to the uncertainty inherent in disposing of such low volumes of material. Instead, it describes various disposal methods that may be employed and estimated a $12 per 100 lbs. (cwt) of CMPAF disposal cost (including transportation costs) for the low-cost end of the range of disposal methods. The cost to dispose of the CMPAF is estimated to range from $7.72 million to $9.97 million annually. Additional on-farm disposal of dead and nonambulatory disabled cattle is expected to increase compliance costs from about $1.02 million to $2.53 million annually (including labor and equipment). The annual revenues foregone from meat and bone meal (MBM) sales due to the prohibition of CMPAF in animal feeds are estimated at $1.41 million to $2.78 million, and foregone tallow sales are estimated at $1.37 million to $2.62 million. This includes the value from CMPAF from cattle 30 months of age or older and cattle not inspected and passed for human consumption regardless of age, as well as from whole carcasses of cattle not inspected and passed for human consumption that could not be rendered due to this proposed rule.

We considered including a provision in this proposed rule that would limit the use of all tallow in animal feed to that which contains no more than 0.15 percent insoluble impurities, not just tallow derived from the materials proposed to be prohibited in animal feed that contains no more than 0.15 percent insoluble impurities. Analysis of this alternative concluded that it would result in annualized costs of about $1.78 million. These costs would consist of capital and operating costs for polishing centrifuges that would be needed by a small segment of independent renderers. We have not included a provision requiring that all tallow meet the 0.15 percent limit in the proposal because the CMPAF ban would effectively negate the risk of infectivity in non-CMPAF-derived tallow. We invite public comments and data on the need for, and impacts of, a provision that would require all tallow used in animal feeds meet the 0.15 percent limit.

TABLE 1.—TOTAL COSTS ($ MILLIONS)

Cost Item	One-Time Cost	Annual Costs	Annualized Costs[1]
Slaughter Facilities			
Capital Investments	$0.56	N/A	$0.08
Labor		$0.60	$0.60
Lost Value of MBM (cattle 30 months of age or older, cattle not inspected and passed)		$1.41—$2.76	$1.41—$2.78
Lost Value of Tallow (cattle 30 months of age or older, cattle not inspected and passed)		$1.37—$2.62	$1.37—$2.62
Disposal of cattle not inspected and passed			
Labor		$0.12—$0.29	$0.12—$0.29
Equipment		$0.9—$2.23	$0.9—$2.23
Renderer Facilities			
Capital Investments	$3.11–$7.67	$0.04—$0.11	$0.49—$1.20
Labor		$1.40—$3.45	$1.40—$3.45
Disposal of CMPAF from cattle 30 months of age or older, cattle not inspected and passed		$7.72—$9.97	$7.72—$9.97
CMPAF Marking (High Estimate)		$0.01	$0.01
Recordkeeping/Labeling	$0.10	$0.05	$0.06
Feed Substitution		$0.30—$0.46	$0.30—$0.46
Proposed Rule Total Costs	$3.76	$13.91—$22.56	$14.44—$23.75

[1] Annualized costs equal to annual costs plus one-time costs at 7 percent over 10 years. Using a 3 percent rate, annualized costs equal $23,535,000.

FDA believes that this proposal, when evaluated in terms of its incremental cost-effectiveness at reducing risks from BSE, is more consistent with efficient science-based risk management than other regulatory approaches that it identified in the 2004 ANPRM. This proposal limits use of animal tissues for which infectivity is high relative to

tissue weight. Weight is a key determinant of the incremental costs from excluding tissues from rendering for animal feed. The approach adopted in this proposal is likely to be relatively cost-effective because it is directed primarily at those tissues for which infectivity is likely to be high relative to control compliance costs.

In the 2004 ANPRM, FDA stated it was considering prohibiting a larger list of cattle tissues (the full SRM list) from use in all animal feeds. Under this option, 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 over 30 months of age or older, including the tonsils and distal ileum of all cattle regardless of age. Additionally, this option would prohibit the small intestine of all cattle, all material from nonambulatory disabled cattle, all material from cattle that are not inspected and passed for human consumption, and MS beef. Lastly, tallow derived from other prohibited materials and containing more than 0.15 percent insoluble impurities would also be prohibited from use in all animal feeds under this SRM option. As detailed later in the analysis of alternatives, we have not included all of these measures in this proposed rule because we believe the proposed rule adequately addresses the risk from the presence of the highest risk cattle material in the animal feed chain. We also note that the proposed rule offers a more cost-effective approach to achieving nearly the same level of protection against the spread of BSE with regard to the presence of high-risk material in the non-ruminant feed supply.

The approach described in the 2004 ANPRM is itself a refinement of an approach announced early in 2004. In January 2004, shortly after USDA reported finding a BSE-infected cow in Washington State, HHS announced its intention to amend the current animal feed regulations by adding several materials to the list of substances prohibited from use in ruminant feed (Ref. 27). These materials included mammalian blood and blood products; inspected meat products that have been cooked, offered for human food, and then further heat-processed for feed (such as plate waste and used cellulosic casings); and poultry litter. Further, FDA planned to require establishments that manufacture, process, blend, or distribute both products containing mammalian-derived proteins and ruminant feed to use separate equipment or facilities in their manufacture, processing and handling.

Preliminary analysis of the regulatory approach described in the January 2004 announcement (Ref. 27) suggests that it is relatively less effective in risk reduction compared to the CMPAF and SRM bans because it would not remove the highest risk tissue (brain and spinal cord) from animal feed channels. Instead, the approach described in the January 2004 announcement would continue to allow the highest risk cattle material in non-ruminant feed, but includes measures intended to prevent cross-contamination of ruminant feed. Although we have not been able to quantify the risk reduction associated with the approach announced in January 2004, it is comparable in costs to the full SRM ban described in the 2004 ANPRM. As a result we are not proposing it here.

In developing this proposed rule we also considered other alternatives (not included here), including combinations of bans of various cattle tissues, from cattle of various ages (>30 months and <30 months) and various states (slaughtered for human food, deads, downers). All of these resulted in costs over $100 million per year with potential infective tissue reductions between 80 percent and 99 percent, when compared to the base case scenario.

Table 2 of this document lists the proposed rule (the CMPAF ban), the SRM ban, and one of the options mentioned previously, namely a ban on brain and spinal cord from slaughter cattle 30 months of age or older, and a ban on the entire carcass of all dead and downed cattle. The table lists both the expected costs of these options, and our best estimate of the percent reduction in cattle tissues known to harbor BSE infectivity. The proposed rule would reduce cattle oral ID50s (the amount of infective material that would result in a case of BSE in 50 percent of the cattle that consumed it) that are available for use in animal feed by about 90 percent as much as a ban on the full list of SRMs (option 3), while imposing only 7 to 10 percent of the costs of the SRM option (0.07 = $14 million/$195 million; 0.10 = $24 million/$240 million). The second option would reduce the cattle oral ID50s by more than 90 percent (a less than 10 percent increase over option 1), but would impose costs that are about five to nine times greater than option 1, though still only about 50 percent to 70 percent of the costs of option 3. Based on the level of protection provided against the spread of BSE and its cost-effectiveness, we believe the proposed rule to be the most appropriate. FDA seeks further comment and scientific and risk information on this analysis of additional regulatory options for strengthening animal feed safeguards.

TABLE 2.—COST-EFFECTIVENESS OF ALTERNATIVE POLICIES

Option (Description of Banned Tissues/Materials)	Infectivity Reduction[1]	Annual Cost ($ millions)
CMPAF list from (1) Cattle 30 months or older, (2) deads, (3) downers and (4), MS beef if CMPAF not removed from carcass, dedicated equipment/container requirement; tallow restriction (proposed rule)	90%	$14—$24
Brain and spinal cord from cattle 30 months or older, carcasses of all deads and downs, MS Beef	>90%	$115—$135[2]
Full SRM list from cattle 30 months or older, tonsils and distal ileum from cattle of all ages, carcass of all deads and downers, MS beef, tallow restriction	>99%	$195—$240

[1] Percent of ID_{50}s from an infected animal that would be banned from use in animal feed.
[2] Detailed cost estimate of this alternative is not included in the regulatory flexibility analysis section of this document.

B. Need for Regulation

Executive Order 12866 directs agencies to assess the need for any significant regulatory action and an explanation of how the regulation will meet that need. In this instance, FDA tentatively concludes that private incentive systems for both suppliers and purchasers in markets for cattle, rendering, and ruminant feed may inadequately address the risk of BSE. This market failure is a result of inadequate information being available to buyers of potentially infective animal feed. Because of the risk of cross contamination during feed production and the risk of inadvertently feeding non-ruminant feed to ruminants on an integrated farm, buyers of ruminant and non-ruminant feed would likely value a decrease in risk of BSE transmission if the market were able to provide it. Buyers, however, have little information about the BSE infectivity of feed because the costs to them of ascertaining infectivity are very high and higher than the costs to the feed producers. As a result, buyers may, without the current or proposed feed rules, unknowingly buy feed contaminated with BSE because of the presence of CMPAF.

The potential market failures created by the continued use of materials that this proposed rule would eliminate are the same as in the 1997 ruminant feed final rule. If feed purchasers could easily identify the risk of the infective agent associated with products from specific suppliers, they could more easily reduce these risks by refusing to buy feed products derived from ruminants known to have consumed prohibited CMPAF. Feed purchasers are unlikely to obtain the information they need due to the long incubation period for BSE that could lead to a suboptimal level of risk prevention by purchasers during the incubation period. Ruminant producers have no way of knowing whether a particular batch of feed or feed ingredients intended for ruminants are free of potentially infective proteins due to the possibility of CMPAFs being introduced through cross-contamination with feed or feed ingredients intended for non-ruminants.

C. Benefits

The purpose of the proposed rule is to further reduce the risk of BSE spreading within the cattle population. Reduced risk of BSE among cattle also reduces human exposure to variant Creutzfeldt-Jakob disease (vCJD) believed to be caused by consumption of beef products contaminated with the BSE agent as well as increases the potential for exports by reducing foreign governments' concerns about the quality of U.S. beef. In this section, we first address the reductions in the risk of BSE to cattle in the United States and the corresponding protection of human health from the major provisions of the proposal. We then summarize the available evidence about the likely effect of this proposed rule on U.S. exports of beef and other livestock products.

1. Risk Reduction

FDA estimates that banning CMPAFs from use in any animal feed would effectively remove about 90 percent of any remaining potential infectivity from possible spread through the feed system. To derive this estimate of the risk reduction from the proposed CMPAF ban, 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 the risk of new BSE cases as the percentage reduction in infectious material. A 1999 report by the Scientific Steering Committee of the European Union suggests that the brain and spinal cord constitute 89.7 percent of the total infective load in a case of BSE (Ref. 28). This rule would prohibit use in all animal feed of these tissues (CMPAFs) from cattle 30 months of age or older and all cattle not inspected and passed for human consumption. CMPAF, when taken from slaughtered 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. Thus, banning CMPAF would effectively remove about 90 percent of total infectivity from animal feed. The absolute level of animal health risk reduced by this rule would depend on the number of infected animals in the United States and the extent to which cattle get exposed to infected material.

The potential human exposure to infectious materials from consuming beef is already small since USDA and FDA prohibit the use of certain cattle materials, including SRMs, from human food. In its preliminary analysis (Ref. 26), USDA modified the Harvard-Tuskegee model and estimated that the two interim final rules issued in January 2004 reduced human exposure to infectious materials by an average of 80 percent. For example, USDA estimated if 5 BSE infected bulls were introduced in 2003 and its control measures take effect in 2004, consumers would be exposed to 4 animal ID50s between 2004 and 2020 compared to 18.5 animal ID50s without these measures (Ref. 26, Table 13). The estimate of percent reduction in exposure is insensitive to the assumed number of infected animals introduced into the United States. To the extent this rulemaking further reduces the likelihood of the spread of BSE, it further reduces the already small likelihood of human exposure to the infectious material.

Assessing the public health implications from estimates of the human exposure to the BSE agent is difficult because there is no agreed upon dose-response relationship between human exposure to cattle ID50s and vCJD cases. Nonetheless, the experience of the United Kingdom suggests that the BSE agent is many times less infective in humans than in cattle. During the 1980s and 1990s, in the absence of preventive control measures, millions of ID50s may have been available for consumption by residents of the United Kingdom, since each cow with clinical symptoms of BSE contains about 7,800 ID50s. The cumulative number of definitive or probable vCJD cases identified in the United Kingdom as of September 1, 2005, is 157 (Ref. 29). Thus, human exposure to a few, or even a few dozen ID50s, may represent a relatively small risk to public health. FDA solicits additional information on the dose response relationship between ID50s and incidence of vCJD.

2. Increased Export Potential

A second major category of benefits pertains to the potential for increased exports of U.S. cattle products to countries that have acted to curtail exports since the discovery of the infected cow in Washington State in December 2003. However, we are unable to quantify the value of such increased exports, because of limits to the data and resources available to us. We note however, that USDA assessed this category of benefits in the interim final regulation that it issued in January 2004. In its assessment, it concluded that "the 2004 beef export demand forecast has been reduced by 90 percent" (Ref. 26, page 58). It reported that U.S. exports of beef, veal, and variety meats amounted to $3.8 billion in sales in 2003, and exports of live cattle resulted in an additional $63 million. The preventive measures contained in this proposed rule are expected to increase the likelihood that foreign governments ease some restrictions on imports of U.S. beef products and cattle.

Another indirect and incomplete measure of the potential benefits of this rule can be seen in measures of the commodities markets' reactions to the discovery of BSE cases. When the first BSE case was reported in Washington

State on December 23, 2003, beef prices had risen to record highs, but were expected to decline in 2004. After the discovery of the BSE case, the 5 area monthly weighted average steer price reported by USDA's Agricultural Marketing Service declined by about 14 percent from December 2003 to February 2004 (Ref. 30). By April 2004, the weighted average monthly price appeared to recover much of the loss. Although never fully reaching pre-BSE record levels, prices by mid–2004 appeared to be close to what they would have been had the BSE-infected cow not been identified. Such volatility in commodities markets may adversely affect independent beef producers who are risk averse and have hedged against such risks inadequately. To the extent that this proposed rule would prevent the development of a BSE-infected cow in the U.S., it may provide benefits to such beef producers by reducing their risk of financial loss and the cost to them of insuring against such risks.

D. Costs

We address the costs to industry of complying with this proposed regulation by considering in turn each of the individual provisions of this proposal. The costs of this proposed rule can be estimated as the sum of the costs of the different provisions.

FDA contracted with ERG to prepare an analysis of the impacts of the ban or restriction on use of CMPAF in proposed

§ 589.2001. Additionally, ERG analyzed the likely impacts of alternative options (on file at the Division of Dockets Management (see ADDRESSES) and henceforth referred to as the Alternatives Report) (Ref. 31)). In particular, these alternatives include the following: (1) A prohibition on the use of specified risk materials in animal feed, (2) the requirement for the use of separate facilities or equipment by those that process both mammalian protein prohibited in ruminant feed and ruminant feeds, and (3) a ban on the use of blood and blood products in ruminant feeds. The ERG analysis of this proposed rule presents estimates of costs for the meatpacking or slaughtering, rendering, and animal producer sectors. In addition, the ERG report provides estimates of impacts on representative small firms in the sectors that are impacted, to a significant degree, to fulfill requirements of a regulatory flexibility analysis. In the development of the Alternatives Report, ERG contacted establishments in the FDA inspection database that were likely to be affected by these regulatory options. Two separate telephone surveys were conducted, covering feed mills, renderers, and agricultural product transporters (the latter including trucking services at feed mills, renderers, and contract haulers). In some cases, written questionnaires were provided to the industry members. In addition, ERG used the services of industry consultants and other contractors for their technical expertise. The sector-specific surveys taken by ERG for the analysis of alternatives were each administered to fewer than ten industry members. In its development of the report on the proposed rule that would prohibit the use of CMPAF in animal feed, ERG again contacted industry members it had identified through its previous work on alternative policies, as well as industry consultants and industry associations.

A study prepared for an industry association concluded that about 35 percent of cattle (42 percent by weight) not inspected and passed for human consumption are currently rendered (Ref. 32). Our analysis estimated the number of cattle at about 17 percent. Whereas our analysis is based on other industry-supplied data that may be less dated, the industry analysis is based on USDA/APHIS data, that while older, resulted from several different USDA surveys.

The industry association's analysis differs from our analysis in the following three ways: (1) The percentage of animals currently rendered, (2) the number of animals, and (3) the weight of prohibited cattle material from each animal. Because of these differences, it may be potentially misleading to make a direct comparison of the findings of the two analyses. For example, if we substitute industry's percentages of animals currently rendered into our analysis, our estimate increases from 17 percent to 33 percent, but not to the industry association's estimate of 35 percent. The slight difference between our findings and those of industry (i.e., 33 percent compared to 35 percent) should be attributed to the difference in the number of animals rendered in each individual category of cattle.

Aside from the percentage of cattle not inspected and passed for human consumption currently rendered, the biggest source of variation between the two estimates can be attributed to the assumptions about the weight of CMPAF being rendered. The industry analysis assumed that the entire carcass would be affected by the ban on cattle not inspected and passed for human consumption. Discussions between ERG and industry experts convince us that, in most cases, renderers can adequately separate CMPAF from the other parts of a carcass. Adjusting the industry analysis to include only CMPAF and to include the same number of cattle as used in our analysis, decreases their estimate of the percentage of tissues rendered from 42 to 33 percent. This contrasts to our finding that only 17 percent of the volume of CMPAF from cattle not inspected and passed for human consumption is currently rendered.

Nevertheless, we acknowledge the uncertainty in all of these estimates. Due to the significance of this factor in estimating compliance costs for this proposed rule, we have adopted the 42 percent figure as the upper bound of the acceptable range and include cost estimates using this factor, where appropriate, within the cost methodology developed in the ERG analysis.

In general, the proposed ban on the use of CMPAF would impose three types of costs. First, it requires firms to buy equipment and to reallocate workers to change their production processes. This requirement imposes direct costs. Second, it prohibits the use of CMPAF by renderers who would use it to produce MBM and tallow. This prohibition reduces the revenue to slaughterhouses that sell CMPAF. Third, it also may oblige the buyers of MBM to turn to alternative ingredients that may be more costly or nutritionally inferior. Furthermore, prohibitions on the use of CMPAF in animal feeds can impose additional disposal costs, insofar as a previously valuable commodity is now turned into an undesirable by-product that requires disposal. Thus, we assess the lost revenue, direct costs, additional disposal costs, and feed substitution costs that may result from this proposed rule.

1. Lost Value of CMPAF

The proposed rule would prohibit the use of CMPAF in all animal feeds. Our analysis concluded that the proposed rule would cause slaughtering operations to incur additional capital investment costs and labor costs to modify and operate their plants in order to separate CMPAF from the rest of the cattle offal. Further, we project the value of the MBM and tallow based on historical prices, and discusses possible CMPAF or MBM disposal options for the industry. We also project the costs of additional disposal of on-farm dead and nonambulatory disabled cattle, CMPAF marking costs, recordkeeping, and labeling costs required by the proposal.

ERG used industry data to estimate the CMPAF quantities that would be removed from cattle 30 months of age or

older slaughtered for human food and cattle not inspected and passed for human consumption based on various factors including the age of the cattle, size of slaughter plant (federal or state inspection authority), and, for dead and nonambulatory disabled cattle of any age, the type and size of animal (beef or dairy cattle). ERG also used industry data on yield to project MBM and tallow production resulting from the current level of CMPAF quantities. Using 4-year averages of byproduct market prices ($180/ton for ruminant or mixed species MBM, and $360/ton for tallow), the annual value of the MBM and tallow originating from CMPAF is estimated at $976,000 and $794,000, respectively. Using the high end of the range discussed previously, the annual value of MBM and tallow would be $1,714,000 and $1,194,000, respectively. Additionally, the annual value of the MBM and tallow from the carcasses of deads and nonambulatory disabled cattle that would no longer be collected by renderers (and would likely be disposed of on the farm) is estimated by ERG at $430,000 and $576,000, respectively. The high end of this range of costs is estimated at $1,064,000 for MBM and $1,422,000 for tallow. The total value of the loss of MBM is estimated to range from $1,406,000 to $2,777,000, and the total value of the lost tallow is estimated to range from $1,370,000 to $2,616,000. The cost of the proposed provision that restricts tallow based on an impurity level is addressed in a later section of this analysis.

2. Direct Costs

There are 5 categories of direct costs, including: (1) Capital and labor for slaughtering and rendering, (2) the tallow restriction, (3) MS beef restriction, (4) CMPAF marking costs, and (5) labeling and recordkeeping costs. We turn to each of these below.

a. *Capital and labor costs—slaughtering and rendering.* The proposed rule would result in cattle slaughter operations separating CMPAF and arranging for its disposal separate from other cattle offal. This change in activity may be similar to the new activities required by the 2004 USDA interim final rule, pertaining to the prohibition of SRM for use in human food. It is likely, however, that SRM segregation activities required under the 2004 USDA interim final rule that banned SRM from use in human foods would differ to some extent from those that would result from this proposed rule. The 2004 USDA interim final rule, for example, would allow SRMs that are no longer available for human consumption to go to rendering for processing into MBM and tallow for use in feed for non-ruminant animal species. Under the FDA proposal, the CMPAFs (which are a small subset by volume of SRMs) could not be used in any animal feeds. Therefore, slaughterers would need to use separate offal lines for offal of non-CMPAF-origin and offal of CMPAF-origin.

For projected capital investment and labor, because of the relatively small volume of CMPAF per plant, and current high rate of brain and spinal cord removal, the rule should result in only modest compliance costs. After consulting with slaughter operations, ERG projected that all slaughter facilities would need additional offal bins designated solely for CMPAFs. Additionally, modifications of processes and procedures would be necessary for those slaughter facilities that handle larger volumes of animals. These offal bin and modification estimates ranged from only $150 for the smallest facilities up to $15,000 for the two largest operations in the United States. Aggregate one-time capital expenditures are estimated to be about $555,000, or about $79,000 annually (based on a 7-percent discount rate over 10 years).

Additional labor costs would be incurred at slaughtering facilities to handle CMPAF segregation and disposal. ERG, using its discussion with industry members, estimated that the smallest facilities would incur no additional labor costs, while the level of additional labor would range from only a few minutes at the next smallest facilities to slightly more than one production worker at the largest establishments. Based on the average pay for this worker of $20,420 (plus a 40 percent increase for benefits), ERG estimated the additional labor costs for this industry at $597,000. Per facility labor costs are expected to range from $313 annually for the smallest plants to $30,000 annually for the largest plants. Total capital and labor costs for slaughtering facilities are estimated at $676,000 ($597,000 in labor costs plus $555,000 annualized at 7 percent over 10 years; annualizing at 3 percent would reduce the cost by about $14,000 annually).

Renderers would also incur additional capital and labor costs to handle CMPAF segregation from cattle not inspected and passed for human consumption. After consulting an equipment manufacturer, ERG projected the cost of equipment purchases and installation for renderers based on the size of the operation. These costs ranged from about $7,300 at the smallest rendering operations to about $72,000 for the largest operations. Total capital costs for renderers are estimated at $3.1 million (annualized at $442,000 over 10 years at a 7-percent discount rate, or at $486,000 with a 10 percent maintenance cost included). Using the upper end of the range of cattle not inspected and passed for human consumption that are currently rendered, we estimate the capital costs for renderers at about $7.67 million (annualized at $1.09 million over 10 years at a 7 percent discount rate, or at $1.20 million with a 10 percent maintenance cost).

Renderer labor costs would also increase due to the CMPAF separation, segregation and disposal. Using the same labor rates as slaughterers, ERG projected that the additional labor would range from slightly over $1,000 at the smallest facility to about $56,500 at the largest facilities. The low end of the range of total incremental payroll costs at renderers are estimated at about $1.4 million annually. The high end of the range of annual labor costs is estimated at $3.5 million. Although no labor overhead is included, we believe it would be negligible because most facilities would hire less than one additional laborer. Total capital and labor costs at rendering establishments are projected to range from about $1.88 million to $3,938,000 annually ($1.4 million to $3.5 million in labor costs plus $486,000 in capital costs after annualizing at 7 percent over 10 years; annualizing at 3 percent would reduce costs by about $78,000).

b. *Tallow restriction.* The proposed rule would ban the use of tallow derived from the brains and spinal cords of cattle 30 months of age or older, the brains and spinal cords of all cattle not inspected and passed for human consumption, and the entire carcass of cattle not inspected and passed for human consumption, if the brains and spinal cords are not removed. An exception to this ban is provided for tallow from these sources that has no more than 0.15 percent insoluble impurities. We do not believe, however, that it would be economical for renderers or tallow manufacturers to further process the brains and spinal cords from these animals into tallow while complying with the proposed equipment separation and tallow purification requirements. We have, therefore, not included additional costs for this proposed provision. The lost value of this tallow (and MBM) has already been accounted for earlier in this analysis.

c. *MS beef restriction.* We do not project any compliance costs for the proposed MS beef provision. The proposed rule would prohibit the use of

MS beef from use in animal feeds if the brain and spinal cord of cattle 30 months of age or older, the brain and spinal cord of all cattle not inspected and passed for human consumption, or the entire carcass of cattle not inspected and passed for human consumption has not been previously removed from the cattle material used to make MS beef. USDA and FDA have already banned MS beef from use in human food. Through contacts with industry members, the analysis projected that about 20 firms, about one-half of which are renderers, would be affected by this proposed provision. These businesses, known as "4D" firms, collect dead and downer (nonambulatory disabled) cattle and sell the meat to pet food manufacturers, zoos and other animal feeding operations. The number of pet food manufacturers using this MS beef as an input has been declining in recent years, however, due to public perceptions concerning pet food inputs. The analysis assumes many of these firms use mechanical separation equipment as part of their operation. Census data does not separately estimate the sales volume of red meat from 4D animals and MS beef from 4D animals. ERG estimated the size of the market at about $100 million per year, based on an industry contact. Further, the analysis estimated that 75 percent of the value of this product is generated from revenues unrelated to the animal or carcass pick-up fees. Of this 75 percent, about 20 percent to 25 percent is believed to represent MS beef sales. Industry contacts report that the brain and spinal cords of dead and downer cattle are already removed prior to any mechanical separation of muscle tissue, thereby negating the need of further compliance efforts. We invite public comment and analysis of the proposed rule's expected impact on 4D animals and current 4D industry practices related to MS beef.

d. *CMPAF marking costs.* The proposed rule would require that renderers that handle CMPAF or products containing CMPAF mark this material or product so that it can be identified by visual inspection. The analysis determined that the use of dyes would most likely be used as the marking agent. Although the industry lacks experience with the use of these dyes, it is believed to be a relatively simple process that would be performed at the end of the rendering process. Using a range of current dye costs, ERG estimated total industry compliance costs of this requirement to be from about $1,700 to $13,000 per year. At the high end of the range of cattle not inspected and passed for human consumption, compliance costs of this provision would range from about $2,200 to $16,000 per year.

e. *Labeling and recordkeeping/access costs.* The proposed rule would require additional measures be taken by renderers that handle CMPAF or products containing CMPAF to ensure that the prohibited materials are not used in animal feed. The proposed requirements include labeling the material "Do not feed to animals", establishing and maintaining records sufficient to track cattle materials prohibited in animal feed to ensure such material is not introduced into animal feed, and making such records available to FDA. The proposed rule would also require renderers that handle any cattle materials to establish and maintain records sufficient to ensure that materials rendered for use in animal feed do not contain CMPAF. ERG judged that the proposed labeling and recordkeeping requirements would result in modest additional costs to all renderers. Although past FDA rulemakings have shown that labeling requirements can impose a substantial cost on industry, the analysis assumed that this rulemaking's simple new labeling requirements (applying primarily to bulk shipments) could be incorporated into current labeling practices. We solicit comment on this assumption. Likewise, any recordkeeping rules would only require incremental administrative activities (to modify procedures and periodically review and file) beyond current renderer recordkeeping requirements. Total industry costs are estimated at about $62,000 annually (one-time costs of $101,000 annualized at 7 percent over 10 years plus annual costs of $48,000). We anticipate that records access costs would be negligible. We invite public comment on the projected level of effort by industry and estimated compliance costs of the proposed labeling and recordkeeping/access requirements.

3. Disposal Costs

After separation from the material allowed to be used in animal feed, an estimated 64.3 million lbs. of CMPAF would no longer be rendered for use in animal feeds, and therefore would need to go to disposal. The analysis identified five options for the disposal of these SRMs. These options include landfilling of the CMPAFs without rendering, rendering for disposal, disposal through alkaline hydrolysis digesters, incineration, and composting. Due to the relatively small volume of CMPAFs, rendering for disposal option would likely not be economically viable. Contacts with industry members elicited various responses concerning the disposal method that would be employed under the CMPAF scenario. While landfilling the CMPAF may be a possibility in some areas, other states do not allow the disposal of animal carcasses in landfills. Our analysis concluded that landfilling would likely be one of several methods used to dispose of the CMPAFs.

Based on industry information gathered for both this analysis (the CMPAF option) and the Alternatives Report, ERG estimated the disposal costs at $12 per 100 lbs. (cwt) of CMPAF. This is substantially higher than its estimate in the Alternatives Report of the cost of SRM disposal. Higher per cwt transportation costs (which are included in the $12 per cwt estimate) are expected under the CMPAF scenario than under the SRM alternative due to the much smaller volume of materials requiring disposal under the CMPAF option. Other reasons for the higher disposal cost rate include. the uncertainty in the disposal methods that will be used, and limited industry experience with at least some of these methods. This led ERG to project a conservative estimate that fully accounts for some uncertainty in cost factors. It is possible that future industry efficiency in CMPAF disposal under any of the disposal methods would lead to a reduction in projected $12 per cwt disposal cost. Nevertheless, the 64.3 million lbs. of CMPAF that would result under this proposed rule is estimated to result in $7.72 million in disposal costs ($6.19 million to slaughterers and $1.53 million to renderers). Using the 42 percent estimate of cattle not inspected and passed for human consumption, we estimate that the 83.1 million lbs. of CMPAF would result in disposal costs of about $9.97 million annually.

Cattle producers are also expected to incur additional disposal costs for cattle not inspected and passed for human consumption in the form of an increase in on-farm disposals. An increase in pick-up fees for cattle not inspected and passed for human consumption due to the slight loss in value of the rendered MBM would likely cause some of these animals to be disposed of at a lower cost (than the pickup fee) to the producer by burial on the farm. As previously discussed, our analysis estimated that about 17 percent of all cattle not inspected and passed for human consumption are currently rendered. Additionally, it predicted that about 26,000 less cattle (0.6 percent of all cattle not inspected and passed for human consumption, or about 3.5 percent of all cattle not inspected and

passed for human consumption that are rendered) would be disposed of in this manner, comprised of beef cows (no additional feedlot cattle included) and cattle under 500 lbs (calves). ERG estimates of the incremental labor and equipment cost of this activity sum to $1.02 million annually. Using the 42 percent estimate of cattle not inspected and passed for human consumption and the same 3.5 percent relative change in the reduction in renderer pick-ups of cattle not inspected and passed for human consumption, we project that at the high end of the range about 64,000 additional cattle would no longer be rendered, at a disposal cost of about $2.53 million.

In forecasting the change in percentages to be disposed on-site, the analysis considered in qualitative terms all factors in the formula renderers use to determine whether they will make pickups. These factors include the travel distance to the location and the expected quantities of animals to be recovered at the location. All pickup charges vary over time with the value of meat and bone meal and tallow, so pickup patterns are subject to market-driven price changes that are addressed in the agreements between renderers and dead animal suppliers.

The analysis also considered that exclusions of prohibited materials reduced the prospective value of the animals to be recovered. Further, the potential latitude for renderers to increase fees was considered, although renderers were fairly tentative in their own forecasts of whether and how much they might increase pickup charges in response to a potential new regulation.

ERG also considered that many relatively remote locations had already been excluded from renderer pickups due to price and regulatory changes over the past ten years. Thus, remaining pickup locations were likely to have reasonably favorable characteristics, although presumably some locations remained marginal in terms of the existing market economics. The data in Table 2–1 of the ERG report (market prices of rendered materials, and MBM and tallow yields) and data on animal weights was used to consider the value of the dead animal to the renderer.

The final forecast of the response in pickups is the judgment of the apparent significance of the regulatory change to the economics of the renderer pickups. Because the brain and spinal cord exclusion affected a relatively small portion of the animal carcass for nondecomposed animals, it followed that the effect on rendering economics was similarly fairly modest. The analysis concluded that the prohibition of these materials would not trigger wider, rippling effects through the renderers' situation.

While there was considerable data about market prices for rendered products and other aspects of pickup economics, data on the distribution of relative costs among dead animal suppliers across the United States was lacking. Such data would have been needed to make a more rigorous forecast of the likely changes in rendering pickup patterns. Given the dominating importance of local economic considerations in rendering economics, even a national distribution of such data would have been of uncertain value to the estimation process.

The industry association report (Ref. 32) (submitted in response to the 2004 ANPRM seeking comment on a more restrictive full SRM ban in animal feed) asserts that there would be no incentive to pick-up cattle not inspected and passed for human consumption if it is banned from animal feed absent exorbitant fees. While this proposed rule would not ban all tissues from cattle not inspected and passed for human consumption, we acknowledge some uncertainty in the response by renderers in this area due to this proposed rule. We request comment on the number and percent of cattle not inspected and passed for human consumption that are currently rendered, as well as the expected number of additional cattle that would be disposed of on farms or elsewhere due to this proposed rule, and the costs of this activity.

4. Feed Substitution Costs

In both FDA's proposed and final rules concerning the prohibition on the use of mammalian proteins in ruminant feeds in 1997, the agency included the cost of feed that would be substituted for the MBM that would be prohibited from use in ruminants. The same issue arises with the proposed rule's creation of a list of CMPAFs that would be prohibited from use in animal feeds. Animal feed manufacturers would substitute other protein sources for the MBM that was previously manufactured from CMPAF.

In the analysis prepared for the 1997 rule banning the use of mammalian protein in ruminant feeds, the agency assumed a $31.76 per ton price increase ($38.33 adjusted to expected 2005 dollars by the average of general inflation from 1997 through 2004) for the substitute material, in this case soybean meal, as well as additional minerals that would be required to provide the same nutritional level as MBM. We accept this as a conservative estimate of the long-term price differential. The price differential between the two varies constantly based on the weather, feed ingredient imports, slaughter rates, and other factors. Since January 2004, soybean meal has been priced from $58/ton below MBM to $55/ton above MBM (Ref. 33).

We cannot predict the future price differentials between the two feed substitutes, but accept the previous number of $38.33/ton as a reasonable current estimate. Applying this feed cost increase over the 7,800 tons of MBM that would not be created as a result of this proposed regulation as calculated by ERG, results in $299,000 in additional feed costs. Using the high end estimate of the number of cattle not inspected and passed for human consumption that are currently rendered, additional feed costs would amount to about $457,000. We invite comment and data on the feed substitution costs that this proposed rule would impose.

5. Distribution of Impacts of CMPAF From Cattle 30 Months of Age or Older Slaughtered for Human Consumption and Cattle Not Inspected and Passed for Human Consumption

ERG, primarily for the purposes of the Regulatory Flexibility Analysis described in more detail below, estimated that a portion of the costs to slaughterers will be passed through to consumers and animal producers. Similarly, a portion of the costs to independent renderers for handling CMPAF from cattle not inspected and passed for human consumption will likely be passed back to ranchers, dairy farmers, and feedlot operators by way of increased pickup or disposal fees. We request public comment and data on the relative size and distribution of the likely pass through of the impacts of this rulemaking.

ERG also addressed the relative importance of the loss of MBM due to the CMPAF prohibition to both integrated packer/renderers and independent renderers. This analysis projected reductions of up to 0.2 percent of MBM production at independent renderers, while reductions of less than 0.1 percent of MBM production would occur at integrated slaughterers (packer/renderers)as the low impact estimates. Using the high estimate of cattle not inspected and passed for consumption that are currently rendered, we project a reduction of up to 0.4 percent of MBM production at independent renderers. Independent renderers rely to a greater extent on deadstock and, with the January 2004 USDA rule banning the use of nonambulatory disabled cattle in

human food, also on nonambulatory disabled cattle as inputs to their production process, while the integrated slaughterers do not.

E. Government Costs

The proposed rule may require the expenditure of additional funds by the Federal government, but the increased expenditures are not expected to be significant. The tissues that would be included on the list of cattle materials prohibited in animal feed, due to this proposed rule, may increase the number of inspections or the length of time necessary to inspect an establishment to verify compliance with the new proposed requirements. However, the number of establishments inspected is not expected to substantially change as a result of this proposed rule. All establishments that would be inspected for compliance under proposed § 589.2001 would already be subject to § 589.2000 or other federal rules. FDA has not estimated any additional costs due to this based on the assumption that the additional resources would not be significant. We invite comment on the issue concerning additional government resources that would be required by this proposed rule. ERG's discussions with industry members led to the conclusion that no new rendering establishments will be constructed and dedicated to disposal rendering as a result of the CMPAF ban. Without additional renderer establishments subject to this or other FDA regulations, FDA inspection efforts are not expected to noticeably increase as a result of this proposed rule.

F. Sensitivity Analysis

Due to the previously described uncertainty concerning the additional cattle not inspected and passed for human inspection that would no longer be rendered as a result of this proposed rule, we have included a sensitivity analysis around this cost factor. The ERG report projected that an additional 0.6 percent of the current 17 percent of cattle not inspected and passed for human consumption that are currently rendered would not be rendered as a result of this rule and would likely be buried on the farm or elsewhere (a relative reduction of 3.5 percent (0.006/0.17) of the cattle not inspected and passed for human consumption that are currently rendered). Table 3 estimates the total costs of the proposed rule for various estimates including the original 0.6 percent reduction in the number of cattle not inspected and passed for human consumption that are rendered, as well as reductions of 1 percent and 2 percent (representing relative reductions of 5.8 percent (.01/.17) and 11.6 percent (.02/.17), respectively). High end cost estimates (derived from the 42 percent estimate of the number of cattle not inspected and passed for human consumption that are currently rendered) for the same relative percent reductions are also included.

If 42 percent of cattle not inspected and passed for human consumption are currently rendered, and that implementation of this proposal would cause an additional 2 percent of all cattle not inspected and passed for human consumption not to be rendered, then the total incremental costs of the rule would rise to about $36 million per year. FDA solicits comment on the likely effect of this proposal on the percent of cattle not inspected and passed for human consumption that is not rendered and on the costs to society of the disposal methods likely to be used as an alternative to rendering.

TABLE 3. SENSITIVITY ANALYSIS

Reduction in Percent of Cattle Not Inspected and Passed for Human Consumption That are Rendered (Proposed Rule)			
	0.6%	1.0%	2.0%
Total Costs	$14.4—$23.7 million	$16.2—27.8 million	$19.8—$36.3 million

G. Regulatory Flexibility Analysis

1. Small Business Impacts

The Regulatory Flexibility Act requires agencies to prepare a regulatory flexibility analysis if a rule is expected to have a significant impact on a substantial number of small entities. The discussion in this section, as well as data and analysis contained in sections two through four of the ERG report, constitute the agency's compliance with this requirement.

One requirement of the Regulatory Flexibility Act is a succinct statement of any objectives of the rule. As stated previously in this analysis, with this proposed rule the agency intends to strengthen the existing safeguards designed to help prevent the spread of BSE in U.S. cattle, as well as further reduce any risk posed to humans from the agent that causes BSE.

The Regulatory Flexibility Act also requires a description of the small entities that would be affected by the proposed rule, and an estimate of the number of small entities to which the proposed rule would apply. Our analysis focused on renderers and animal slaughterers, and to a lesser extent on 4D firms. Additionally, the Alternatives report addresses possible impacts to small dairy farms from the blood products alternative, and impacts to feed mills from the dedicated equipment/facilities alternative (options summarized in the alternatives section of this document).

Animal slaughterers would be classified in the North American Industrial Classification System (NAICS) under code 311611—Animal (Except Poultry) Slaughtering and renderers under NAICS code 311613—Rendering and Meat Byproduct Processing. The Small Business Administration (SBA) classifies slaughterers and renderers with less than 500 employees as small businesses.

The ERG study estimated the number of small businesses that would be affected by the proposed rule in its analysis of compliance costs. The number of slaughterers and renderers affected by the CMPAF ban (including recordkeeping/labeling and marking costs) were estimated at 689 and 141, respectively. This would include all federally inspected slaughter plants and the all those renderers that handle mammalian proteins that are currently prohibited in ruminant feed. Using U.S. Census and USDA data, ERG then distributed the number of affected entities in each business sector across the size classes of establishments using the same proportions as those presented in the total number of establishments. Using this distribution, it appears that about 97 percent of slaughterer establishments and all renderer establishments would be considered small businesses. However, the existence of many multi-establishment rendering and slaughtering firms would tend to overestimate the number of small businesses within each sector. In fact, other Census data shows that only 79 percent of rendering firms would be considered small businesses (Ref. 34). Nevertheless, we believe that the number of affected small businesses in

both sectors would still be considered substantial.

The CMPAF ban would primarily affect slaughterers and renderers. ERG used its Small Business Impact Model (SBIM) to predict net income and closure impacts for slaughterers and renderers by size of establishment (for a full explanation of the SBIM, see section 4.2 of the Alternatives report (included in the docket (Ref. 31)). The model assumes there is no pass through of compliance costs. Although this is a conservative assumption, smaller businesses in fact are probably less able to pass through compliance costs than larger businesses in the same industry, all other things equal. Under the no pass through assumption, the model predicts moderate net income impacts that could result in the closure of up to one slaughtering and one rendering establishment. We acknowledge that net income impacts would likely be higher under the higher estimate of the percent of cattle not inspected and passed for human consumption that are currently rendered.

Our analysis for simplicity ignores any potential increases in MBM prices that may ensue as a result of this proposed rule. In fact, some modest price increases may occur as foreign demand for MBM increases in response to reduced risk of BSE infectivity. Such price increases may mitigate any reduction in net income of independent renderers.

ERG developed a separate market model to estimate the impact of a CMPAF ban on beef prices and output. It implies that about 50 percent of compliance costs will be passed on to consumers, 38 percent will be passed back to cattle producers, and 12 percent will be incurred by slaughterers. The model predicts that cattle producers would realize only a 0.01 percent reduction in price for cattle, which would not be considered a significant impact. Nevertheless, the agency acknowledges the possibility of significant impacts on a substantial number of small slaughterers and renderers.

The agency believes that the annual feed substitution costs (from about $300,000 to $457,000) would not constitute a significant impact when spread across the thousands of non-ruminant animal producers that currently use ruminant protein in animal feeds. The agency requests comments and additional data on the likely small business impacts on slaughterers, renderers, beef cattle producers, dairy cattle producers, or other animal producers and firms in related industries.

2. Analysis of Alternatives

We considered five other measures that are not included in this proposed rule. These five measures, discussed in turn in the following paragraphs, include: (1) A requirement that those facilities handling both mammalian protein that is currently prohibited in ruminant feed and ruminant feeds use dedicated facilities or equipment for each, (2) a ban on the use of poultry litter in ruminant feeds, (3) a ban on the use of blood and blood products in ruminant feeds, (4) a ban on the use of plate waste in ruminant feeds, and (5) a ban on the use of a larger list of SRM (using the USDA and FDA definition for human food) from all animal feeds.

a. *Dedicated facilities/equipment requirement.* As mentioned previously in this preamble, FDA considered requiring that those facilities that process or otherwise handle both mammalian protein currently prohibited in ruminant feed and prepare feed or feed ingredients for ruminants use separate facilities or equipment in order to prevent cross-contamination. This option was included in the public announcement concerning agency intentions in January 2004. The proposed rule's dedicated equipment requirement concerns the issue of cross-contamination of CMPAFs with other cattle material once it has been separated, whereas the requirement for dedicated equipment/facilities under this option concerns cross-contamination of mammalian protein currently prohibited in ruminant feeds and ruminant feeds under the current mammalian to ruminant feed ban. Due to the large tonnage difference between CMPAFs and all animal protein currently being rendered, this alternative would result in larger industry impacts than would the dedicated equipment requirement concerning CMPAFs alone.

In its Alternatives Report, ERG projects that this option would be expected to reinforce the current trend in which increasing numbers of feed mills discontinue the use of mammalian protein currently prohibited in ruminant feeds in favor of porcine, avian, or plant-based proteins. ERG estimates that only 124 out of more than 5,100 feed mills and 41 out of 235 renderers currently produce ruminant feed or feed ingredients and handle or process ruminant MBM. Based on its small survey of feed mills, ERG estimates that only 27 of these feed mills and 4 renderers would invest in dedicated facilities or equipment in order to continue or begin to distribute both prohibited materials and ruminant feeds or feed ingredients.

ERG consulted an agricultural architecture and engineering firm to prepare cost estimates of investment in dedicated feed mill facilities. Based on these estimates and discussions with feed mill operators, ERG projects that no new mills would be constructed as dedicated facilities to comply with this option, but rather currently operating or idle mills would either be renovated or expanded as dedicated facilities, or would handle a dedicated line of equipment. The annualized costs of these investments for the 27 feed mills were estimated at $6.2 million over 10 years at a 7-percent discount rate (at a 3-percent discount rate over 10 years, the cost would be $5.1 million per year). The effect on the ruminant MBM market caused by the discontinued use by those that currently offer it in feeds but would choose not to invest in dedicated facilities or equipment would be expected to be small.

ERG performed a similar survey of some of the 41 renderers that the FDA inspection database showed as handling mammalian proteins currently prohibited in ruminant feed and produce materials intended for use in ruminant feed. The results of this survey indicate that very few renderers intend to invest in dedicated facilities. Based on its small sample, ERG predicts that only 4 renderers would do so. These were all expected to currently have partial separation or dedication capabilities in place. Based on discussions with renderer operators through this and previous surveys, ERG predicts that the renderers that invest in dedicated facilities would spend, on average, about $2 million each. The total cost of investment in dedicated facilities would be $8 million. Annualizing this total over 10 years at a 7-percent discount rate results in an annual cost of $1.14 million ($940,000 over 10 years at a 3-percent discount rate).

The dedicated facilities/equipment requirement would also extend to the transportation services for mammalian proteins currently prohibited in ruminant feed. Based on another survey of selected feed mills, agricultural trucking companies and renderers concerning their current transportation of products, ERG determined that agricultural transporters would also incur costs as a result of this provision of this option. The option implies that renderer delivery trucks that carry prohibited MBM, including contract haulers providing this service, would no longer be allowed to backhaul ruminant feed or ruminant feed ingredients as part of its delivery routine. Due to this