Introduction

Mr. Chairman, Members of the Committee, thank you for the opportunity to participate in today's hearing on measures taken by the Federal government to safeguard human and animal health in the United States from Bovine Spongiform Encephalopathy (BSE) and the response to the finding of a BSE-positive cow in the State of Washington. I am Dr. Lester M. Crawford, Deputy Commissioner, Food and Drug Administration (FDA or the Agency).

The mission of FDA is to protect the public health by assuring the safety and efficacy of our nation's human and veterinary drugs, human biological products, medical devices, human and animal food supply, cosmetics, and radiation emitting products. In fulfilling this mission, FDA is the Agency responsible for assuring that all FDA-regulated products remain safe and uncompromised from BSE and related diseases. Many FDA-regulated products contain bovine ingredients, for example, heart valves, ophthalmic devices, dental products, wound dressings, injectable drugs, vaccines, soups, gravies, sausage casings, and animal feeds.

FDA has long been actively involved nationally and internationally in efforts to understand and prevent the spread of BSE. FDA collaborates extensively with the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), the Animal and Plant Health Inspection Service (APHIS) and the Food Safety and Inspection Service (FSIS) within the U.S. Department of Agriculture (USDA), Customs and Border Protection (CBP), the Environmental Protection Agency (EPA), other Federal agencies, state and local jurisdictions, and with affected industries and consumer groups. Many of these activities fit within the framework of the Department of Health and Human Service's (HHS or the Department) Bovine Spongiform Encephalopathy/Transmissible Spongiform Encephalopathy (BSE/TSE) Action Plan, which was released in August 2001. This collaboration over many years has enabled FDA to strengthen safeguards for FDA-regulated products and to respond quickly and effectively to the first case of BSE within the U.S.

Executive Summary

The mission of the Agency is to protect the public health by assuring the safety and efficacy of our nation's human and veterinary drugs, human biological products, medical devices, human and animal food supply, cosmetics, and radiation emitting products. In fulfilling this mission, FDA is the Agency responsible for assuring that all FDA-regulated products remain safe and uncompromised from BSE and related diseases.

BSE is a progressive neurological disorder of cattle that results from infection by an unconventional transmissible agent, and was first diagnosed in the United Kingdom (U.K.) in 1986. Many FDA-regulated products contain bovine ingredients, for example, heart valves, ophthalmic devices, dental products, wound dressings, injectable drugs, vaccines, soups, gravies, sausage casings, and animal feeds and thus must be taken into consideration as part the effort to prevent infectivity by BSE.

FDA has a longstanding commitment to protecting consumers from BSE by following multiple measures designed to safeguard FDA-regulated products from possible contamination by the BSE agent. Under the Federal Food, Drug, and Cosmetic (FD&C) Act, FDA has the authority

to prevent the adulteration and misbranding of FDA-regulated products. Further, for medical products that require pre-market approval (e.g., drugs under Section 505 and medical devices under Section 513 of the FD&C Act), FDA has addressed safety concerns related to BSE through requirements of the application and approval process.

The U.S. employs a robust multi-layered approach to preventing the introduction and amplification of BSE. While the goal of this approach is to achieve an extremely high level of compliance with each preventative measure, this multi-layered approach is designed to protect the U.S. consumer from exposure to the BSE infective material, and to date this approach has been working. Since 1989, USDA has prohibited the importation of live animals and animal products from BSE-positive countries. Since 1997, FDA has prohibited the use of certain mammalian proteins in the manufacture of ruminant feed. FDA continues to implement policies to keep safe all FDA-regulated products, including food, food ingredients, dietary supplements, drugs, vaccines, and cosmetics from risk of any BSE-contaminated bovine material. As a result of these multiple regulatory safeguards, the risk of exposure to BSE through products, FDA regulates remains extremely low in the U.S.

FDA's 1997 animal feed regulation forms the basis of the Agency's efforts to prevent the spread of BSE through animal feed. This rule prohibits the use of most mammalian protein in the manufacture of animal feeds for ruminants. FDA implemented this rule to establish in our country feeding practices consistent with the best science and epidemiological knowledge known at the time to prevent the spread of BSE throughout herds of U.S. cattle. A risk assessment sponsored by USDA and conducted by the Harvard Center for Risk Analysis, released in November 2001, identified FDA's feed ban as one of the primary safeguards against the spread of BSE in U.S. cattle.

To maximize protection afforded by the feed regulation, FDA has developed and implemented a BSE/Ruminant Feed Ban Inspection compliance program and established the goal of 100 percent compliance. FDA's strategy for achieving uniform compliance with the feed rule focuses on three areas: education, inspection, and enforcement. FDA and its state counterparts conduct, at least annually, targeted BSE inspections of 100 percent of known renderers, protein blenders, and feed mills processing products containing material prohibited from use in ruminant feed. Compliance by these establishments with FDA's feed rule is estimated to be at better than 99 percent. As of December 20, 2003, FDA had received over 26,000 inspection reports (6,404 for Fiscal Year 2003). The majority of these inspections (around 70 percent) were conducted by state officials for FDA, with the remainder conducted by FDA officials. The total number of inspection reports represents 13,672 firms, 1,949 of which are active and handle materials prohibited from use in ruminant feed. The 1,949 active firms that handle prohibited material have been inspected by FDA and, as of December 31, 2003, only five were found to have significant violations, resulting in official action indicated (OAI). FDA is working with these firms to bring them into compliance.

On December 23, 2003, FDA was notified by USDA of a presumptive-positive finding of BSE in a cow in Washington State. FDA immediately initiated its BSE Emergency Response Plan. As part of the plan, FDA has been coordinately closely with USDA so that we can effectively investigate this BSE case, trace the various products involved, and take the

appropriate steps to protect the public. FDA investigators and inspectors located the high risk material rendered from the infected cow, and the rendering plants placed a hold on the rendered material, which is being disposed of appropriately. I am happy to report that all of the establishments inspected by FDA during the course of the investigation were in compliance with the feed ban. In addition, to help address the concerns of foreign governments and restore confidence in American products, FDA has participated, along with USDA, in numerous meetings and consultations with foreign governments since USDA surveillance found the BSE-positive cow.

In addition to new policies and regulations, new knowledge and tools gained through applied research can greatly help us to be more effective in our regulatory mission, such as protecting the country from BSE. Several of FDA's Centers, as well as many private laboratories, academic institutions, and other Federal agencies (most notably NIH) are also involved in significant research activities relating to TSEs. Basic areas requiring research include: increasing our understanding of prions, learning how prions are transmitted within a species and potentially between species, developing diagnostic tests for humans and animals, developing detection methods for use on regulated products, developing methods to increase or eliminate infectivity, and designing new treatments. We are optimistic about the promise of new technologies, such as better methods to quickly distinguish the species of proteins and sensors to detect abnormal prions in food. Development of these technologies can contribute significantly to the effort to prevent the spread of BSE and must be considered carefully when evaluating potential regulatory changes to address BSE.

At the time that FDA implemented the feed rule in 1997, the Agency also recognized that evolving, complex scientific and public health issues, particularly regarding BSE required the Agency to continue to assess and scrutinize the rule to ensure its integrity as a firewall against the potential for spread of BSE. To further explore ways the animal feed regulation could be improved in November 2002, FDA published an advance notice of proposed rulemaking (ANPR) soliciting information and views from the affected industries and the public on some potential changes to its current feed regulation, including ways that the animal feed regulation could be strengthened. Although the risk of exposure to BSE in the U.S. remains extremely low and the measures in place are working, as a result of the recently discovered infected cow in the state of Washington, the Agency is evaluating the appropriateness of additional science-based measures to further strengthen our current protections.

Yesterday, Department Secretary Tommy Thompson and FDA Commissioner Mark McClellan announced several additional public health measures to further strengthen the current robust safeguards that help protect Americans from exposure to the agent that causes BSE and help prevent the spread of BSE in U.S. cattle. These measures relate to both protections for foods intended for human consumption as well as additional measures to strengthen FDA's 1997 final rule regulating animal feed. With respect to human foods, FDA announced that it will extend to FDA-regulated foods, dietary supplements and cosmetics, restrictions on using specified risk materials that would complement the recent USDA announcements. Concerning animal feed, the Agency announced a series of measures designed to lower even further the risk that cattle will be purposefully or inadvertently fed "ruminant" proteins, including, eliminating an exemption in the feed rule that allows mammalian blood and blood products at

slaughter to be fed to ruminants as a protein source; banning the use of "poultry litter" as a feed ingredient for cattle and other ruminants; prohibiting the use of "plate waste" as a feed ingredient for ruminants, including cattle; and taking steps to further minimize the possibility of cross-contamination of animal feed via equipment, facilities or production lines.

Finally, FDA is increasing its inspections of feed mills and renderers in 2004. Our 2001 base funding for BSE-related activities was $3.8 million. We shifted resources internally in 2001 and received a substantial increase from Congress in 2002. Our funded level for 2004 is currently approximately $21.5 million, almost a five-fold increase over the 2001 base. FDA will itself conduct 2,800 inspections and will make its resources go even further by working with state agencies to fund 3,100 contract inspections of feed mills and renderers and other firms that handle animal feed and feed ingredients. Through partnerships with states, FDA will also receive data on 700 additional inspections, for a total of 3,800 state contract and partnership inspections in 2004. These inspections would include 100 percent of all known renderers and feed mills that process products containing prohibited materials.

The Agency looks forward to continuing to assist Congress as it evaluates the risks associated with BSE, identifies opportunities to promote technologies that will detect and prevent the spread of BSE, and considers science-based approaches to further strengthen regulatory protections and bolster the resources available to assist Federal, state, local and private efforts to assure that BSE does not present a threat to human or animal health in the U.S.

Background on Bovine Spongiform Encephalopathy (BSE)

BSE is a progressive neurological disorder of cattle that results from infection by an unconventional transmissible agent, and was first diagnosed in the U.K. in 1986. It belongs to a family of diseases, transmissible spongiform encephalopathies (TSEs), a group of transmissible, slowly progressive, degenerative diseases of the central nervous systems of several species of animals.

The vast majority of BSE cases have been reported in the U.K., where more than 183,000 cases in more than 35,000 herds have been reported through the end of November 2003. The U.K.-BSE epidemic peaked in January 1993 at nearly 1,000 new cases per week. The original source of the BSE outbreak is uncertain, but may have resulted from the feeding of scrapie-containing sheep meat-and-bone meal to cattle. Scrapie is an endemic spongiform encephalopathy and has been widespread in the U.K., where the rendered carcasses of livestock (including sheep) were fed to ruminants and other animals until 1988, as a protein-rich nutritional supplement. It appears likely that changes in the rendering process in the U.K. that had taken place around 1980 allowed the etiologic agent in infected carcasses to survive, contaminate the protein supplement, and infect cattle. There is strong evidence and widespread agreement that the outbreak was amplified by feeding rendered bovine meat-and-bone meal to young calves. BSE has a prolonged incubation period in cattle, ranging from two to eight years, with a mean of five to six years.

Outside of the U.K., 22 other countries, mostly in Europe, have reported cases of BSE in

indigenous cattle to the World Organisation for Animal Health (known as the O.I.E.). Other countries may be considered at risk because of an inadequate surveillance program, a lack of information on which to make a risk assessment, or the potential for exposure to BSE.

Related Diseases

TSEs also include "scrapie" in sheep and goats, "chronic wasting disease" (CWD) in deer and elk, feline spongiform encephalopathy, transmissible mink encephalopathy, and, in humans, kuru, Gerstmann-Straussler-Scheinker syndrome, fatal familial insomnia, and Creutzfeldt-Jakob disease (CJD or "classical" CJD) and variant CJD, which was first reported in the U.K. in 1996. TSEs are not known to infect non-mammalian species.

Classic CJD occurs throughout the world, including the U.S., at a rate of about one case per million people. The median age at death in the U.S. of patients with classic CJD is 68. Most cases of CJD are considered sporadic, a small number are familial associated with a gene mutation, and a small number are iatrogenic, resulting from the accidental transmission of the causative agent via contaminated surgical equipment, or as a result of cornea or dura mater transplants, or the administration of human-derived pituitary growth hormones.

Variant CJD (vCJD) is a distinct variant from classic CJD and is strongly believed to have been acquired from eating food products containing the BSE agent. The absence of confirmed cases of vCJD in geographic areas free of BSE supports this conclusion, and the interval between the period for initial extended exposure of the population to potentially BSE-contaminated food and the onset of initial vCJD cases, approximately ten years, is consistent with known incubation periods for CJD. Experimental studies on monkeys and mice, as well as additional laboratory studies of infecting prions from vCJD patients and BSE-infected animals, also support such a relationship. The incubation period for vCJD in humans is unknown, but is at least five years and could extend up to 20 years or longer.

As of December 1, 2003, a total of 153 vCJD cases had been reported worldwide, 143 of the cases occurring in the U.K. The low number of vCJD cases relative to the number of cases of BSE in the U.K. indicates that a substantial species barrier protects humans from widespread illness. There are no cases of vCJD having been contracted in the U.S. The only person diagnosed with vCJD while living in the U.S. is a U.K. citizen believed to have acquired the disease while living in the U.K.

Legal and Regulatory Framework for FDA Protections

FDA has a longstanding commitment to protecting consumers from BSE by following multiple measures designed to safeguard FDA-regulated products from possible contamination by the BSE agent. Under the FD&C Act, FDA has the authority to prevent the adulteration and misbranding of FDA-regulated products. For example, FDA has used provisions in Section 402(a) (the food adulteration provisions) and Section 403(a) (the food misbranding provisions) of the FD&C Act to prohibit ruminant feed from containing certain protein derived from mammalian tissues. These same adulteration and misbranding provisions apply to human food. Further, for medical products that require pre-market approval (e.g., drugs under Section 505

and medical devices under Section 513 of the FD&C Act), FDA has addressed safety concerns related to BSE through requirements of the application and approval process. Additionally, when material from the one BSE-positive cow in the U.S. was traced to renderers, FDA advised those firms that this material could not be used as an animal feed because it was adulterated under Section 402(a)(5) of the FD&C Act because it was, in part, the product of a diseased animal. Under section 801 of the FD&C Act, FDA may refuse admission of imported food and certain other products that appear to be in violation of the FD&C Act. Furthermore, under Section 701(a), FDA may promulgate regulations for the efficient enforcement of the FD&C Act. For example, under Section 701(a) and other sections, FDA promulgated its "animal feed" rule (Title 21, Code of Federal Regulation (CFR) section 589.2000) to prohibit ruminant feed from containing certain protein derived from mammalian tissues. In addition, under the Public Health Service Act, FDA is authorized to make and enforce regulations to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the U.S. or between states.

Preventing the Spread of BSE: FDA Protections

FDA and other Federal agencies have had preventive measures in place to reduce the U.S. consumer's risk of exposure to any BSE-contaminated meat and food products for a considerable time. Since 1989, USDA has prohibited the importation of live animals and animal products from BSE-at risk countries. Since 1997, FDA has prohibited the use of certain mammalian proteins in the manufacture of ruminant feed. FDA continues to implement policies to keep safe all FDA-regulated products, including food, food ingredients, dietary supplements, drugs, vaccines, and cosmetics from risk of any BSE-contaminated bovine material. As a result of these multiple regulatory safeguards, the risk of exposure to the BSE agent through products FDA regulates remains extremely low in the U.S. In 1998, USDA commissioned the Harvard Center for Risk Analysis to conduct an analysis and evaluation of the U.S. regulatory measures to prevent the spread of BSE in the U.S. and to reduce the potential exposure of U.S. consumers to BSE. The Harvard study concluded, among other things, that even if introduced in the U.S., due to the preventive measures currently in place in the U.S., BSE is extremely unlikely to become established in the U.S.

The U.S. employs a robust approach to preventing the introduction and amplification of BSE, and the prevention of introduction and amplification of BSE has been described as consisting of five separate firewalls. Our existing firewalls are based on a four-pronged regulatory strategy:

? Our first firewall is formed through regulations and enforcement to protect U.S. borders from potentially infective materials utilizing a regime of import controls. USDA, beginning in 1989, enacted major restrictions on imports, and more restrictive import controls have been introduced as we have learned more about the science of BSE and as the worldwide epidemiology has changed. FDA remains a committed partner with USDA and CBP in protecting our borders.

? The second firewall is surveillance of the U.S. cattle population for the presence of BSE. Surveillance of the cattle population is the primary responsibility of USDA, and USDA has recently announced steps to increase surveillance.

? The third firewall is prevention of the amplification of BSE through feed provided to cattle and other ruminants, and this responsibility falls primarily on FDA. FDA's animal feed ban regulations form the basis of this third firewall and have been cited as one of the most significant elements needed to prevent the spread of BSE in the U.S. We have taken intensive steps to get an extremely high level of compliance with this feed ban. As a result, we have been able to work with the animal feed industry to achieve more than a 99% compliance rate - and we intend to continue to work for full compliance.

? The fourth firewall is making sure that no bovine materials that can transmit BSE be consumed by people. So even if a BSE-positive cow made it through all of the previous firewalls, which is extremely unlikely, it would not pose any risk to people. USDA and FDA have long had steps in place to help prevent any possible exposure to BSE in bovine products, and recently USDA announced additional major steps to prevent any of the tissues known to carry BSE from entering the beef supply, as well as to restrict use of certain "downer" cows that might be at higher risk of carrying BSE. FDA will be taking comparable measures to prevent human exposure to the FDA-regulated bovine products that might potentially harbor BSE.

? A fifth firewall is effective response planning to contain the potential for any damage from a BSE positive animal, if one is discovered at some point in the system. This urgent response plan went into place immediately upon the discovery of a BSE-positive cow in Washington State on December 23, 2003. We have inspected and traced products at 22 facilities, including feed mills, farms, dairy farms, calf feeder lots, slaughterhouses, meat processors, transfer stations, and shipping terminals. We have accounted for all the products related to the BSE-positive cow that FDA regulates, and none have gone into human or animal consumption. Moreover, FDA has conducted inspections at all the rendering facilities involved, and found they were fully in compliance with our feed rule.

The goal of our firewall after firewall approach is to provide full protection of the public against BSE without adding unnecessary costs or restricting the consumption of safe beef products. FDA and USDA intend to maintain an extremely high level of compliance with each firewall. In addition, our multi-layered approach makes sure that even if each firewall doesn't function perfectly, the U.S. consumer is, nonetheless, protected from exposure to the BSE infective material.

FDA's Feed Rule: Substances Prohibited From Use in Animal Feed

Rendered feed ingredients contaminated with the BSE agent are believed to be the principal means by which BSE is amplified in cattle populations. To help prevent the establishment and spread of BSE through feed in the U.S., FDA implemented a final rule that prohibits the use of most mammalian protein in the manufacture of animal feeds for ruminants. This rule, 21 CFR 589.200, became effective on August 4, 1997. Mammalian proteins exempted from the rule are blood and blood products, gelatin, inspected meat products that 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. Fats and oils, such as tallow, do not fall within the current feed rule because they are not protein.

FDA implemented this rule to establish in our country feeding practices consistent with the best science and epidemiological knowledge known at the time to prevent the spread of BSE throughout herds of U.S. cattle. A risk assessment sponsored by USDA and conducted by the Harvard Center for Risk Analysis, released in November 2001, identified FDA's feed ban as one of the primary safeguards against the spread of BSE in U.S. cattle.

To maximize protection afforded by the feed regulation, FDA has developed and implemented a BSE/Ruminant Feed Ban Inspection compliance program and established the goal of 100 percent compliance. FDA's strategy for achieving uniform compliance with the feed rule focuses on three areas: education, inspection, and enforcement.

A strong inspection presence can be considered the backbone of FDA's strategy for achieving compliance with the feed rule. FDA and its state counterparts conduct, at least annually, targeted BSE inspections of 100 percent of known renderers, protein blenders, and feed mills processing products containing material prohibited from use in ruminant feed. Compliance by these establishments with FDA's 1997 feed rule is over 99 percent. FDA has prioritized the inspection process so that any firms found to be out of compliance in their last inspection will be promptly re-inspected. In addition, FDA will conduct for-cause inspections where evidence dictates, e.g., as a result of a sampling assignment. FDA and the states also conduct inspections of selected processors that are not using prohibited material to ensure compliance with the regulation by this segment of the industry.

Inspections conducted by FDA or state investigators are classified to reflect the compliance status at the time of the inspection based upon the objectionable conditions documented. These inspection decisions are reported as OAI, Voluntary Action Indicated (VAI), or No Action Indicated (NAI).

? An OAI inspection classification occurs when significant objectionable conditions or practices were found and regulatory sanctions are warranted in order to address the establishment's lack of compliance with the regulation. An example of an OAI inspection classification would be findings of manufacturing procedures insufficient to ensure that ruminant feed is not contaminated with prohibited material. Inspections classified with OAI violations will be promptly re-inspected following the regulatory sanctions to determine whether adequate corrective actions have been implemented.

? A VAI inspection classification occurs when objectionable conditions or practices were found that do not meet the threshold of regulatory significance, but do warrant advisory actions to inform the establishment of findings that should be voluntarily corrected. Inspections classified with VAI violations are more technical violations of the ruminant feed rule such as minor record-keeping lapses and conditions involving non-ruminant feeds.

? A NAI inspection classification occurs when no objectionable conditions or practices were found during the inspection or the significance of the documented objectionable conditions

found does not justify further actions.

As of December 20, 2003, FDA had received over 26,000 inspection reports (6,404 for fiscal year 2003). The majority of these inspections (around 70 percent) were conducted by state officials for FDA, with the remainder conducted by FDA officials. The total number of inspection reports represents 13,672 firms, 1,949 of which are active and handle materials prohibited from use in ruminant feed. These firms, which may be in more than one category, include renderers, licensed feed mills, feed mills not licensed by FDA, protein blenders, and others (such as ruminant feeders, on-farm mixers, pet food manufacturers, animal feed salvagers, distributors, retailers, and animal feed transporters). The 1,949 active firms that handle prohibited material have been inspected by FDA and, as of December 31, 2003, only five were found to have significant violations, resulting in OAI. FDA is working with these firms to bring them into compliance.

To be transparent about inspection results, FDA has recorded inspectional findings in a newly designed FDA BSE/Ruminant Feed Inspection Database available on FDA's website. The database is dynamic, with new information being entered on a continual basis. Each entry in the database represents the results of the most recent inspection.
FDA also conducts sampling of feed and feed ingredients in the marketplace as an additional tool to target firms for inspection. This type of sample analysis is being done using feed microscopy as the method for detecting prohibited materials. Other methods, such as polymerase chain reaction (PCR), are being validated for additional analytical use.

Enforcement is an important component of the compliance strategy. FDA pursues enforcement actions when we find knowing or intentional non-compliance, or if repeated inspection and educational efforts are ineffective in assuring compliance. Our first action of choice will ordinarily be a Warning Letter, which notifies responsible parties of a violation or violations and asks for a response within a certain time frame explaining corrective actions taken. When it is consistent with the public protection responsibilities of FDA and the nature of the violation, it is our practice to afford individuals and firms an opportunity voluntarily to take appropriate and prompt corrective action. The Agency has additional, more stringent enforcement tools available when our notification to the company of documented violations does not lead to compliance with the FD&C Act, including product seizure, injunction, and prosecution.

As of January 1, 2004, FDA has issued 63 Warning Letters and has one court ordered Permanent Injunction since the BSE feed rule went into effect. Also, 47 firms recalled 280 products during the same time period; 12 of the recalls were in 2003.

Education has been, and continues to be, a critical component of our compliance strategy. Providing clear guidance and information on FDA's requirements and regulations is vital to help assure compliance. FDA has provided and sponsored many educational services and forums, including nationwide seminars, CD-ROM training, teleconferences, guidances targeted for different segments of the animal feed industry, guidance for Federal and state inspectors, and a variety of published articles. The Agency has met with many industry trade groups to discuss coordination of educational efforts with affected parties, and we expect to continue an open dialogue, seeking suggestions for types of educational approaches, sharing resources, and

keeping the industry updated on new developments or problem areas that arise.

Import Controls

To minimize the risk of the introduction or spread of BSE we also must have strong enforcement measures to protect our borders. FDA's Import Program is responsible for coordinating the import of products potentially infected with or at high risk of infection with the agent associated with BSE. Operationally, FDA's Import Program provides for the review of information about FDA-regulated products offered for entry into the U.S. and the opportunity for physical examination of the products. FDA uses this information to determine whether a product is subject to refusal of admission.

In protecting the borders from potentially unsafe products, FDA works closely with USDA and CBP to ensure a coordinated and efficient BSE import control strategy. This tri-agency cooperative effort has led to a multi-layer review process whereby each agency utilizes the strengths of its particular entry procedures to produce a composite system that is considerably more robust than any one component. BSE import activities are reviewed and coordinated by an inter-agency workgroup composed of representatives from FDA, CBP, and USDA/APHIS. In fact, on February 5, 2002, with APHIS, FSIS, Canadian Food Inspection Agency (CFIA), Health Canada, and state participation, FDA conducted a simulation exercise involving the importation of potentially BSE-contaminated product and subsequent regulatory follow-up.

FDA uses Import Alerts to disseminate information regarding problems or potential problems with imported products. Import Alerts recommend that field offices examine, sample, or detain and, if warranted, refuse admission of the product in question. These Import Alerts are made available on FDA's website. With respect to its import alerts on BSE, FDA coordinates closely with APHIS and its prohibitions on the importation of products related to BSE concerns. An alert may cover an individual manufacturer, supplier, or a particular product from an entire country. Import Alerts also may be issued as a follow-up to an inspection, when it is determined that a manufacturer is in violation of good manufacturing practice requirements.

FDA has in place several import alerts targeting BSE. Import Alert 17-04, first issued in October 1994, allows detention, without physical examination, of bulk shipments of high-risk bovine tissues and tissue-derived ingredients from BSE-at-risk countries. Import Alert 99-25, first issued in January 2001, allows detention without physical examination of animal feed, animal feed ingredients, and other products for animal use from countries identified by USDA as BSE-positive or BSE-at-risk when processed animal protein is declared in the ingredients or when FDA sampling and analysis finds the presence of undeclared animal protein. Import Alert 71-02, issued in October 2003, calls for detention without physical examination of products of specific firms located in USDA-listed BSE-positive or BSE-at-risk countries, which have been identified through FDA sampling and analysis, as importing products containing animal protein. These import alerts are continuously updated as new countries are listed by USDA as either BSE-positive or BSE-at-risk, or to make other appropriate changes.

FDA's Response to the Identification of a BSE-Positive Cow in Washington State

On December 23, 2003, at approximately 3:00 pm, the Agency's Office of Crisis Management

(OCM) was notified by USDA's APHIS of a presumptive-positive finding of bovine spongiform encephalopathy (BSE) in a "downer" cow slaughtered on December 9, 2003, at a USDA-inspected slaughter facility in Washington State.

FDA had in place its Bovine Spongiform Encephalopathy Emergency Response Plan that describes the roles and activities of each of the Agency components involved in managing this kind of emergency. This plan had been tested several times in tabletop and simulated incidents that actively involved state, Federal, and Canadian counterparts. The plan has been in place since 2001 and has been revised in response to the incident exercises conducted by FDA.

As provided in the Emergency Response Plan, OCM's Emergency Operations Center (EOC) is the single point of coordination for FDA's response to a BSE emergency. FDA's EOC maintains contact with HHS Secretary's Command Center (SCC), CDC's EOC, USDA/FSIS Office of Food Security and Emergency Preparedness, and other EOCs, as appropriate.

At the time of notification by USDA of the presumptive case of BSE, FDA's OCM initiated its BSE Emergency Response Plan and activated FDA's EOC. Various FDA headquarters and FDA center offices were immediately notified in accordance with the plan, as well as the FDA Seattle District Office (SEA-DO).

FDA responsibilities include conducting inspections and investigations to determine where any animal by-products went and ensuring that they did not enter commerce contrary to provisions of the FD&C Act and other statutes enforced by FDA.

On the same day FDA was notified of the presumptive case of BSE by USDA, FDA's SEA-DO dispatched five investigative teams to investigate various facilities suspected of being either a source or recipient of affected material.

An aggressive schedule of inspections and investigations was pursued by FDA which enabled FDA to announce in December 27, 2003, that its investigators and inspectors from the states of Washington and Oregon had located the high risk material rendered from the one cow that had tested positive for BSE in Washington State and that the rendering plants that processed this material had placed a hold on the rendered material. The firms, located in Washington State and Oregon, assisted and cooperated fully with FDA's investigation.

FDA advised the involved renderers on acceptable methods of disposing of material, such as landfill (coordinating with state and local officials and EPA), incineration, digestion, or conversion to a fuel/industrial source. Disposal of the meat and bone meal on hold has begun.

Communications, of course, have played a critical role in many aspects of the incident response. Late on December 23, 2003, FDA's headquarters and district staff participated in a teleconference with APHIS and Washington State officials to ensure a coordinated response to the incident. FDA, CDC, Department of Defense, and FSIS continued to participate in APHIS-initiated interagency calls throughout the response to the incident.

FDA also has kept affected industries and State counterparts informed and up-to-date. On December 23, 2003, FDA's Center for Food Safety and Applied Nutrition (CFSAN) advised

Washington State milk cooperatives that there was no known risk of BSE transmission from milk. The scientific data indicate that milk from BSE cows does not transmit BSE.
In responding to the BSE incident, FDA inspected and traced products at many different facilities, including renderers, feed mills, farms, dairy farms, calf feeder lots, slaughterhouses, meat processors, transfer stations, and shipping terminals. Notably, inspectors found no deviations from FDA's feed rule.

Working with Foreign Governments

FDA officials regularly meet with representatives of foreign governments and international organizations on many levels and on many issues of common interest, including BSE. Immediately after the announcement on December 23, 2003, of a BSE-positive cow in the U.S., various foreign governments closed their markets to U.S. beef. Since that time, FDA officials, working closely with USDA officials, have been involved in numerous meetings and consultations with representatives of foreign governments to help address concerns and restore confidence in American products. For example:

? FDA representatives met with Japanese officials from the Ministry of Agriculture, Forestry, and Fisheries, the Ministry of Health, Labor, and Welfare, the Food Safety Commission and the Japanese Embassy on January 9, 2004, to discuss BSE control measures in animal feed and food additives.

? FDA representatives met with numerous foreign attaches at USDA on January 12, 2004, to discuss FDA's Center for Veterinary Medicine measures to prevent BSE in animal feeds.

? FDA representatives met in separate meetings on January 13, 2004, with officials from the CFIA and from Mexico's Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación to discuss current feed safety measures to prevent BSE in the U.S.

? The Ministers of Agriculture of the U.S., Mexico and Canada met on January 16, 2004, to coordinate ongoing interagency efforts towards expediting increased harmonization through a consultative process among the countries. I accompanied Secretary of Health and Human Services Tommy G. Thompson, at this meeting that resulted in a proposal to establish a Coordinating Committee on BSE to facilitate collaborative effort.

? Additionally, last week I visited with Japanese and Korean officials, as part of the U.S. Government's delegation to discuss scientific and trade implications of the U.S. BSE case. The delegation also included senior scientific, regulatory, and trade officials from USDA, and the U.S. Trade Representative.

Research

Several of FDA's Centers, as well as many private laboratories, academic institutions, and other Federal Agencies (most notably NIH) are involved in significant research activities relating to TSEs. Basic areas requiring research include: increasing our understanding of prions; learning how prions are transmitted within a species and potentially between species; developing

diagnostic tests for humans and animals; developing detection methods for use on regulated products; developing methods to increase or eliminate infectivity; and designing new treatments.

Most people envision research as being applied by medical practitioners to diagnose and treat disease. Applied research also is critical in a regulatory environment, where knowledge and tools gained through applied research can help us to achieve our mission more effectively and more efficiently.

Taking one example pertinent to BSE, current rendering processes do not completely inactivate the BSE agent. Advances in technology that could distinguish between BSE-infected and non-infected cattle, or that could completely inactivate the BSE agent in feed components may allow for exemptions to the feed regulations for those renderers and feed manufactures who apply these technologies.

Discussed below some examples of research on BSE and vCJD that could have significant regulatory implications and benefit:

? FDA's CFSAN is in the final year of funding a two-year project to develop sensors to detect abnormal prion protein in food. Work on the project should be completed in early 2004, and will result in a report on the usefulness of the sensors for detecting TSE agents in finished food products.

? No tests for the rapid diagnosis of vCJD have been validated as either sufficiently specific or sensitive to be used to screen the blood supply. A reliable blood-screening test for vCJD is an extremely important goal and is currently the object of considerable research activity.

? FDA has conducted and supported research efforts in the process of validating a rapid-DNA based method for detection of animal derived materials in animal feed and feed ingredients. As a part of this research effort, FDA has developed a Polymerase Chain Reaction probe to determine the animal species of origin from which feed ingredients were derived.

FDA remains firmly committed to bringing better science to the public, to provide better public health protection at a lower cost. That's why a key part of our BSE strategy involves fostering the development of better technologies to deal with BSE. To enhance the ability of our public health system to detect prohibited materials in animal feed, FDA will continue to support the development and testing of diagnostic tests to identify prohibited materials. As these tests are developed FDA will evaluate the utility of such tests promptly and thoroughly, so that there will be a quick and reliable method of testing animal feeds for prohibited materials.

Additional Measures to Bolster Protections Against BSE

FDA implemented the feed rule in 1997 based on the best information obtainable on the science and epidemiology of BSE at the time. The Agency also recognized that evolving, complex scientific and public health issues, particularly regarding BSE and vCJD, required the Agency to continue to assess and scrutinize the rule to ensure its integrity as a firewall against the

potential for spread of BSE.

The Agency held a public hearing in October 2001 to solicit information and views on its present animal feed regulation. FDA requested information and views from individuals and organizations on the present rule and whether changes in the rule or other additional measures were necessary. The Agency was particularly interested in soliciting comments and views from individuals, industry, consumer groups, health professionals, and researchers with expertise in BSE and related animal and human diseases. The Agency specifically invited comments, both oral and written, on 17 questions about ways the rule and its enforcement might be improved to achieve its original objectives of preventing the establishment and amplification of BSE in the U.S. Transcripts of the hearing were then made publicly available with access through FDA's website.

Soon after the public hearing, the USDA released the Harvard Center for Risk Analysis's findings on the impact of various risks and potential pathways for exposure of U.S. cattle and U.S. citizens to the BSE agent. This assessment of the situation in the United States concluded that, due to control measures already in place, the risk to U.S. cattle and to U.S. consumers from BSE is very low. The model also demonstrated that certain new control measures could reduce the small risk even further.

To further explore ways the animal feed regulation could be improved in November 2002, FDA published an ANPR soliciting information and views from the affected industries and the public on some potential changes to its current feed regulation, including ways that the animal feed regulation could be strengthened. Information and comments were sought on the following five aspects of the BSE feed regulation: feasibility and impacts of excluding high risk materials, such as brain and spinal cord, from rendered animal products; use of poultry litter in cattle feed and impacts of banning such use; impacts of introducing new labeling requirements for pet food; methods to prevent cross-contamination between prohibited and non-prohibited material; use of plate waste in ruminant feed and impacts of eliminating such use.

Yesterday, we announced that we will be taking several additional steps to further strengthen the current robust safeguards that help protect Americans from exposure to the agent that causes BSE and help prevent the spread of BSE in U.S. cattle. These measures relate to both protections for foods intended for human consumption as well as additional measures to strengthen FDA's 1997 final rule regulating animal feed. Many of these steps were raised in the November 2002, ANPR, as well as at the public meeting. With respect to human foods the Agency announced it will be extending to FDA-regulated foods, dietary supplements and cosmetics, restrictions on using specified risk materials that would complement the recent USDA announcements. Concerning animal feed, the Agency announced a series of measures designed to lower even further the risk that cattle will be purposefully or inadvertently fed "ruminant" proteins, including, eliminating the existing exemption in the feed rule that allows mammalian blood and blood products at slaughter to be fed to ruminants as a protein source; prohibiting the use of "poultry litter" as a feed ingredient for cattle and other ruminants; banning the use of "plate waste" as a feed ingredient for ruminants, including cattle; taking further steps to minimize the possibility of cross-contamination of animal feed via equipment, facilities or production lines; and evaluating additional mechanisms to enhance the ability of our

public health system to detect prohibited materials in animal feed utilizing diagnostic tests.

In addition, FDA intends step up its inspections of feed mills and renderers in 2004. FDA is increasing its inspections of feed mills and renderers in 2004. Our 2001 base funding for BSE-related activities was $3.8 million. We shifted resources internally in 2001 and received a substantial increase from Congress in 2002. Our funded level for 2004 is currently approximately $21.5 million, almost a five-fold increase over the 2001 base. FDA will itself conduct 2,800 inspections and will make its resources go even further by working with state agencies to fund 3,100 contract inspections of feed mills and renderers and other firms that handle animal feed and feed ingredients. Through partnerships with states, FDA will also receive data on 700 additional inspections, for a total of 3,800 state contract and partnership inspections in 2004. These inspections would include 100 percent of all known renderers and feed mills that process products containing prohibited materials.

Conclusion

FDA has an enormous responsibility in assuring that the products the Agency regulates which contain bovine materials are safe and uncompromised by BSE or other TSEs. FDA's principal line of defense in meeting this responsibility is to cut-off all avenues for the possible spread of BSE through U.S. cattle herds. Our most powerful tool in preventing the spread of BSE in U.S. cattle herds is effective enforcement of the Agency's feed ban restrictions as part of a multi-layered set of firewalls put in place as part of the U.S. Government's comprehensive BSE prevention program.

To date, a rigorous program of education, inspections, and enforcement education have enabled us to fulfill our responsibilities as part of the U.S. plan for preventing the spread of BSE. Although the risk of exposure to BSE in the United States remains extremely low and the measures in place are working, as a result of the recently discovered infected cow in the state of Washington, the Agency will be taking additional science-based steps to further strengthen our current protections.

FDA looks forward to continuing to assist Congress as it evaluates the risks associated with BSE, identifies opportunities to promote technologies that will detect and prevent the spread of BSE, and considers science-based approaches to further strengthen regulatory protections and bolster the resources available to assure that BSE does not present a threat to human or animal health in the U.S.

Thank you for the opportunity to testify today.