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FDA VETERINARIAN

RUMINANT FEED (BSE) ENFORCEMENT ACTIVITIES

To help prevent the establishment and amplification of BSE through feed in the United States, FDA implemented a final rule that prohibits the use of most mammalian protein in feeds for ruminant animals. This rule, Title 21 Part 589.2000 of the *Code of Federal Regulations*, became effective on August 4, 1997. To date, active monitoring by the U.S. Department of Agriculture (USDA) has found no cases of bovine spongiform encephalopathy (BSE) in U.S. cattle.

This is an update on FDA enforcement activities regarding the ruminant feed (BSE) regulation. FDA previously provided information on this issue in three CVM UPDATEs, most recently one on July 6, 2001.

FDA's enforcement plan for the ruminant feed regulation includes education, as well as inspections, with FDA taking compliance actions for intentional or repeated non-compliance. As part of the enforcement plan, an initial inspection assignment was issued to all FDA District Offices in 1998 to conduct inspections of 100% of all renderers and known feed mills to determine compliance. Additional assignments have been issued to FDA District Offices regarding (1) further initial inspections of previously unknown firms potentially handling materials prohibited in ruminant feed and (2) re-inspections of firms found on initial inspection to be out of compliance with this regulation.

FDA's Center for Veterinary Medicine (CVM) has assembled data from the inspections that have been conducted AND whose final inspection report has been submitted to CVM (i.e., "inspected/reported") as of October 26, 2001. There is a lag time between the completion of an inspection and the submission of a final inspection report to CVM. This lag period includes the time required to conduct quality assurance on the report and to evaluate the findings before a final report is submitted.

As of October 26, 2001, CVM had received inspection reports covering inspections (both initial inspections and re-inspections) of 10,018 different firms. The majority of these inspections (around 80%) were conducted by State officials under contract to FDA and the remainder by FDA officials.

Various segments of the feed industry had different levels of compliance with this feed ban regulation.

(Continued, next page)

U.S. VETERINARIANS AID ENGLAND IN FMD OUTBREAK

by Charles Eastin, D.V.M., Ph.D., M.P.H., M.B.A.


Photo by Charles Eastin

A farmer inspects his livestock near Danby, North Yorkshire. As a result of England's FMD outbreak, his livestock is all that remain in this valley.

Foot and Mouth Disease (FMD) has ravaged the English countryside this year. Diseased animals have been found on approximately 2,030 farms, resulting in the killing of diseased and susceptible livestock on more than 9,500 farms. More than 600,000 cattle, 3 million sheep and 100,000 pigs have been killed as part of the effort to eradicate FMD in England. Many fields throughout the country that were once filled with livestock now stand empty.

All cloven-hooved animals are susceptible to FMD, which is caused by an enterovirus of the Picornoviridae family. England's current outbreak has been attributed to the highly virulent PanAsia O type virus. The disease does not readily infect humans. In the few documented human cases throughout history, symptoms were mild and followed by a complete recovery. While FMD is endemic in many countries of the world, most developed nations have eradicated

(Continued, top of page 3)

In This Issue

The results to date are reported here both by "segment of industry" and "in total".

RENDERERS

(These firms are the first to handle rendered protein and send materials to feed mills and ruminant feeders.)

- Estimated number of rendering firms in the U.S. – 264
- Number of firms that have received an initial inspection – 264
- Number of firms whose initial inspection has been reported to CVM – 232
- Number of firms handling materials prohibited for use in ruminant feed – 174 (75% of those firms inspected/reported).
- Of the 174 renderers handling prohibited materials, at their most recent inspection (could have been an initial or a follow-up inspection):
  - 8 (5%) had products that were not labeled as required
  - 6 (3%) did not have adequate systems to prevent co-mingling
  - 2 (1%) did not adequately follow record keeping regulations
  - 13 (7%) firms were found to be out of compliance (some firms were out of compliance with more than one aspect of the rule)

FDA LICENSED FEED MILLS

(FDA licenses these mills to produce medicated feed products. This licensing has nothing to do with handling prohibited materials under the feed ban rule: 21 CFR 589.2000. A license from FDA is not required to handle materials prohibited under 21 CFR 589.2000.)

- Number of FDA licensed feed mills in the U.S. as of October 26, 2001 – 1,231
- Number of firms that have received an initial inspection – 1,240
- Number of firms whose initial inspection has been reported to CVM – 1,181
- Number of firms handling materials prohibited for use in ruminant feed – 406 (34% of those firms inspected/reported)
- Of the 406 licensed feed mills handling prohibited materials, at their most recent inspection (could have been an initial or a follow-up inspection):
  - 24 (6%) had products that were not labeled as required
  - 25 (6%) did not have adequate systems to prevent co-mingling
  - 3 (1%) did not adequately follow record keeping regulations
  - 42 (10%) firms were found to be out of compliance (some firms were out of compliance with more than one aspect of the rule)

FEED MILLS NOT LICENSED BY FDA

(FDA does not know the total number of these feed mills because they are not required to be licensed by FDA.)

- Estimated number of feed mills not licensed by FDA in the U.S. – 6,000-8,000
- Number of firms whose initial inspection has been reported to CVM – 4,835
- Number of firms handling materials prohibited for use in ruminant feed – 1,439 (30% of those firms inspected/reported
- Of the 1,439 feed mills not licensed by FDA handling prohibited materials, at their most recent inspection (could have been an initial or a follow-up inspection):
  - 133 (9%) had products that were not labeled as required
  - 78 (5%) did not have adequate systems to prevent co-mingling
  - 82 (6%) did not adequately follow record keeping regulations
  - 228 (16%) firms were found to be out of compliance (some firms were out of compliance with more than one aspect of the rule

OTHER FIRMS INSPECTED

(Examples of such firms include: ruminant feeders, on-farm mixers, protein blenders, and distributors.)

- Estimated number of such firms in the U.S. – unknown
- Number of firms whose initial inspection has been reported to CVM – 4,237
- Number of firms handling materials prohibited for use in ruminant feed – 629 (15% of those firms inspected/reported)
- Of the 629 such firms handling prohibited materials, at their most recent inspection (could have been an initial or a follow-up inspection):
  - 56 (9%) had products that were not labeled as required
  - 21 (3%) did not have adequate systems to prevent co-mingling
  - 27 (4%) did not adequately follow record keeping regulations
  - 81 (13%) firms were found to be out of compliance (some firms were out of compliance with more than one aspect of the rule)

TOTALS *(as of October 26, 2001)*

- Number of firms whose initial inspection has been reported to CVM – 10,018

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FDA Veterinarian

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the disease and ban the import of certain animal products to keep the disease out. In countries where the disease persists, economic losses are mainly due to decreased feed conversion and loss of export markets.

On February 20, 2001, FMD was confirmed in England. The disease was traced to a pig farm in Heddon-on-the-Wall, a suburb of Newcastle-Upon-Tyne in Northumberland. It is believed to have entered the country in meat that was illegally imported into England and served at a restaurant. Uncooked garbage from this restaurant was believed to have been fed to pigs that became infected with the FMD virus. Garbage can be fed legally to pigs in England provided that such feeding is accomplished under license and in accordance with applicable laws that specify the process by which garbage must be processed (i.e., it must be macerated and cooked). Because of extensive animal movement, the disease had spread throughout the country before authorities became aware of its presence. While farmers received full market value as compensation for every animal killed, this provided little solace for the loss of years, perhaps lifetimes, of effort put into the careful breeding of prime stock. In addition to the trauma and uncertainty for individual farmers, the activities that would normally help them to cope with loss were also disrupted. Biosecurity concerns resulted in the cancellation or closure of livestock markets, agricultural fairs and other activities that normally provide an opportunity for farmers to discuss and work through their problems. Even in these hard times, most farmers in the area felt a sense of duty to cooperate with authorities and willingly submitted to a cull of their livestock if the livestock became infected. Farmers know the tremendous impact FMD has on livestock production and markets.

Drs. Charles Eastin (FDA/CVM) and John Poe (Lexington, Kentucky) review a map of outbreak at Thirsk, North Yorkshire.

The State Veterinary Service in England normally employs approximately 300 veterinarians. Due to the large number of FMD cases, the British government's Department of Environment, Food, and Rural Affairs (DEFRA) invited the U.S. and many other countries throughout the world to assist them by sending veterinarians to work in England (generally for periods of 30 days). Veterinarians from all over the world responded to the call, and more than 1,000 Temporary Veterinary Inspectors (TVIs) were employed by DEFRA. The United States Department of Agriculture (USDA Animal and Plant Health Inspection Service, Veterinary Services, Emergency Programs) responded to the request and has sent hundreds of veterinarians to England to assist in the fight to eradicate FMD from the country. The USDA actively recruited U.S. veterinarians from many sources, including those employed by Federal, State and local governments, academic institutions, and clinical practices. In addition to providing needed assistance to England, the U.S. will greatly benefit by having a reservoir of veterinarians experienced in FMD identification, outbreak management, and multinational animal disease eradication efforts.

Teams of veterinarians from the U.S. arrived in London weekly. Upon arrival, veterinarians would proceed to DEFRA's main office on Page Street for orientation. The following day they would move to a regional office for additional training and possible assignment to a satellite office. TVIs

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RUMINANT FEED (BSE) ENFORCEMENT ACTIVITIES (Continued)

- Number of firms handling materials prohibited for use in ruminant feed – 2,501 (25% of those firms inspected/reported)
- Of the 2,501 firms handling prohibited materials, at their most recent inspection (could have been an initial or a follow-up inspection):
  - 204 (8%) had products that were not labeled as required
  - 116 (5%) did not have adequate systems to prevent co-mingling
  - 106 (4%) did not adequately follow record keeping regulations
  - 333 (13%) firms were found to be out of compliance (some firms were out of compliance with more than one aspect of the rule. These 333 firms will be re-inspected in the near future.)

RE-INSPECTIONS

When firms are found to be out of compliance with the feed ban rule, FDA lists them for a re-inspection. As of October 26, 2001, reports of 1,719 re-inspections have been submitted to CVM. On re-inspection of these 1,719 firms, 108 (6%) were found still to be out of compliance with this rule. Firms previously found to be not in compliance have corrected problems through a variety of ways, including further training of employees about the rule, developing systems to prevent co-mingling, re-labeling their products properly, and adhering to record keeping regulations. Other firms have achieved compliance by eliminating prohibited materials from their operations.

□

were most commonly assigned to field positions, where they would be involved in:

1) conducting surveillance of farms to detect FMD soon after infection
2) culling of farms where disease had been detected
3) investigating suspected cases reported by farmers
4) providing second opinions for TVIs that were on farms where FMD was suspected
5) conducting risk assessments for farmers that appealed the decision that their animals be culled
6) oversight of biosecurity on farms

When FMD was detected on a farm, the farm was designated as an "infected premises" or IP. For 21 days from the time disease was diagnosed, disease surveillance visits were conducted on the surrounding area farms (those within 3 kilometers of the IP) every two days. On a surveillance visit, veterinarians examined animals to detect disease. All supplies used on farms were kept in the trunk (or "boot", as they say in England) of the vehicle instead of the back seat. Every effort was made to keep the interior portion of the vehicle clean and disease-free. Upon arrival at the farm, the veterinarian would park the vehicle outside of the farm gate on a public roadway with the trunk directed toward the farm entrance. To drive onto any farm (even one on which disease had not been diagnosed and was not suspected) would be considered a breach of biosecurity and may result in a vehicle unknowingly spreading disease. Biosecurity was particularly important considering that there were a limited number of veterinarians and many farms to be visited. If paperwork was required on the farm, it was placed in a plastic bag prior to the veterinarian getting out of the cab of the vehicle. This bag would also be disinfected before taking it onto the farm. The papers would be removed from the plastic bag to be completed while in the farmhouse and then returned to the plastic bag for transport back to the vehicle. A "disinfection line" consisting of a tub of disinfectant with a stiff-bristle brush and sponge was set up just outside of the trunk. Any equipment or supplies that the veterinarian needed to carry onto the farm were thoroughly disinfected and placed at the end of the disinfection line, perhaps in a bucket. The veterinarian would cover his or her clothing with disposable paper coveralls and a rubber suit. To prevent the spread of disease by footwear, boots (or "Wellingtons") were kept in the trunk of the vehicle and disinfected before proceeding onto each farm. Rapid reliable communication was essential should disease be detected on the farm during the surveillance visit. Cellular phones, particularly susceptible to moisture, were double bagged. To prevent the spread of disease, the phones remained in the plastic bags when they were used on the farms.

Generally, the farmer would meet the veterinarian and they would proceed to inspect and examine each susceptible animal on the farm. In addition to his or her role in disease detection, the veterinarian also provided advice on biosecurity measures taken by the farmer to keep disease off of the farm. Also, the social value to the farmer of interaction with the veterinarian was not insignificant as many of these areas were under stringent biosecurity restrictions that effectively prevented many of the social gatherings that are a hallmark of normal rural life.

If the veterinarian didn't find any infected animals, he or she would exit the farm. All equipment, including boots and the rubber suit was thoroughly cleaned and disinfected prior to being returned to the trunk of the vehicle. Paper suits and any other disposable supplies were placed in plastic biohazard bags, double bagged and returned to the main office for incineration.

However, if the veterinarian suspected disease in any of the animals, the entrance to the farm would be blocked immediately to minimize the chance of any further spread of the disease. After calling the office to report the disease, a more experienced veterinarian would arrive to provide a second opinion regarding the presence of disease. The main DEFRA office in London would then be called and the final diagnosis decision was made within hours of the veterinarian having arrived on the farm. Testing was considered a confirmation of the decision, but test results are not timely enough to be considered in the decision making process.

Handheld Global Positioning System (GPS) devices (part of the standard kit issued to veterinarians) were used to determine the exact location of the infected animal(s) on IPs. From this location, the three-kilometer surveillance zone was established. Within 24 hours of the time of FMD diagnosis, all susceptible animals on the IP were killed. In addition, within 48 hours, all susceptible animals on the farms adjacent to the IP were killed. The animals on adjacent farms were killed because there is an extremely high likelihood that they were already, or soon would be, infected.

Because of the ease with which FMD can be transmitted, extreme biosecurity measures were required

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A Cleaning and Disinfection team sprays personnel with disinfectant after a long day on a cull site.

on FMD positive farms, especially during the killing process. After confirming the diagnosis, the veterinarian would start the paperwork and prepare for a long afternoon (which frequently stretched late into the night). Office personnel arranged for required teams to converge on the IP within hours following diagnosis. Required teams included:

1) case officers who acted as assistants to the veterinarian in charge
2) an appraiser to value the animals for compensation purposes
3) a slaughter team to kill the adult animals
4) a headchute (or crush) with gates to ensure safe handling of livestock
5) animal handlers
6) a biosecurity team to ensure that all personnel and equipment entering and leaving the farm were properly disinfected, and for post-cull disinfection of the animal carcasses and area of the kill
7) leak-proof truck(s) (or lorries) to haul the animals away from the farm for later incineration
8) front-end loader(s) to load the animals into the trucks
9) an escort to follow the truck(s) and ensure they did not leak

Perhaps one of the most important tasks of the veterinarian was to ensure that the killing of animals was performed in a proper and humane manner. Young animals were killed by injection of euthanasia solution by veterinarians, while older animals were stunned with a captive bolt by slaughter personnel and killed by inserting disposable pithing rods through the brain and into the spinal canal immediately following stunning. One reason for the use of disposable pithing rods was to eliminate the possibility (albeit remote) that workers would be exposed to the etiological agent that causes Bovine Spongiform Encephalopathy.

Occasionally, a farmer would appeal the culling decision because he or she didn't think that his or her livestock had been exposed to FMD. These appeals were frequently based on a belief that good biosecurity on the farm and/or distance from the IP resulted in a low risk that these animals were infected. In such situations, a veterinarian would conduct a thorough risk assessment to assess the likelihood that animals on the farm had been exposed to disease. This risk assessment was forwarded to epidemiology personnel for further consideration. This assessment included an interview of farm personnel, thorough inspection of facilities (including biosecurity measures taken by the farmer and personnel), measurement of the distances between the farm in question and the IP, and inspection of all susceptible livestock.

The total economic cost of the FMD outbreak in England has been estimated to be 2.4 to 4.1 billion British pounds (about 3.4 to 5.8 billion U.S. dollars). Nationally, twenty-five percent of English firms have been impacted. An FMD outbreak in the U.S., either deliberate or accidental, could easily cost many times this amount. This knowledge should help to reinvigorate every individual's vigilance to keep this and other exotic diseases from entering or re-entering the U.S. Undoubtedly, some diseases will gain entrance into the U.S. In these cases, early detection and eradication are essential to ensure the damage to the U.S. livestock industry is minimized. Travelers should be cognizant of the risks of bringing food and animal products into the U.S. from overseas (see websites listed below). Veterinarians should work to educate farmers about what symptoms are suggestive of exotic diseases. Farm workers should educate themselves about the usual symptoms of these diseases and keep them in mind when they inspect their livestock. Lastly, farmers should contact a government veterinarian immediately if the symptoms are suggestive of an exotic infectious disease. Our collective efforts will help to maintain the health of our livestock industries and keep our animals free of foreign animal diseases like FMD.

For additional information on FMD or England's FMD experience, visit one of the following websites:

- USDA Vesicular Diseases Education Website – *http://www.aphis.usda.gov/vs/ep/fad_training/VESVOL7/vesindex.htm*
- USDA APHIS, FMD Information for Travelers – *http://www.aphis.usda.gov/oa/fmd/index.html*
- USDA APHIS, Veterinary Services, Emergency Programs – *http://www.aphis.usda.gov/vs/ep/*
- Department of Environment, Food, and Rural Affairs (England) – *http://www.defra.gov.uk/footandmouth*
- DEFRA Biosecurity videos (England) – *http://www.defra.gov.uk/footandmouth/farmers/biosecurity/biosecurity.htm*
- Office International Des Epizooties – *http://www.oie.int/eng/maladies/en_alpha.htm*

Dr. Eastin is a Veterinary Medical Officer in CVM's Division of Epidemiology. He was a DEPRA Temporary Veterinary Inspector working on FMD during July and August 2001. □

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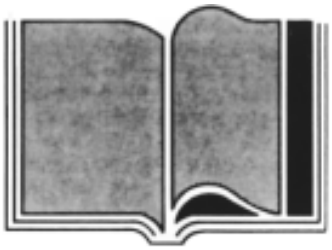

The Center for Veterinary Medicine has recently published "Judicious Use of Antimicrobials for Pork Producers." This publication was prepared in conjunction with the National Pork Board. Copies are available by contacting the Communications Staff (HFV-12), Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855, or contacting the CVM Web site: www.fda.gov/cvm. □

6 CVM SUPPORTS RESCUE EFFORTS

by Karen A. Kandra

We at CVM remember the victims and their families in our thoughts and prayers. Following the tragic terrorist attack on America, people are finding ways to help the rescue efforts by contributing to numerous assistance organizations. At CVM, many employees bought almost 200 t-shirts featuring the American Flag from Special Tees, Inc., a Rockville, MD business. The proceeds went to support the Montgomery County, MD's Urban Search and Rescue Team, known as Maryland Task Force 1, who was deployed to the Pentagon to assist with rescue efforts. The Urban Search and Rescue Task Force is a highly specialized group of fire fighters, paramedics, and civilian specialists. President Bush visited with the team members to express his personal gratitude for their hard work. For more information, visit their website at *http://www.co.mo.md.us/dfrs/mdtf1/*.

Many people wanted to contribute to an animal-related organization, and we became aware of ongoing efforts in New York City to rescue pets left behind by victims. Employees of CVM contributed more than $1,000 to the World Trade Center Animal Relief Fund to assist in rescue efforts by the Humane Society of New York.

The Humane Society of New York is conducting a major rescue operation in the wake of the attack on the World Trade Center, encompassing care and support for animals harmed or left homeless through the disaster. Directly after the attack, the Society's veterinarians were the first to begin emergency triage at Pier 40, near "Ground Zero". They attended more than 200 animals at the Pier, and served as medical escorts for individuals going into sealed apartments to retrieve pets. Medical staff continues to be ready on standby, to render emergency off-site care as needed.

The Society's veterinary hospital is now treating significant numbers of animals daily, suffering severe dehydration, respiratory distress, corneal inflammations, and other traumas. They have established a network of foster homes for cats, dogs, birds and other small animals needing temporary or permanent relocation. In addition, they have set up a Relief Center at their facility for people who have lost their homes, or those who have rescued a displaced pet but are not yet equipped to care for it. All are welcome to free care and supplies including pet food, bowls, carriers, leashes, litter and litter boxes. For further information, please visit *http://www.humanesocietyny.org*.

Karen Kandra is a Consumer Safety Officer in CVM's Communications Staff, and Editor of the ***FDA Veterinarian***. □

FDA LEADERSHIP DEVELOPMENT PROGRAM

by Monica Brown-Reid, D.V.M.

Building Leaders for the Future

For the participant, the FDA Leadership Development Program is a twelve-month endeavor, which provides a broad range of experiences to groom a future leader at the FDA. It is designed for FDA employees in grades 12, 13, and 14 and Commissioned Officers 04 and 05 whose goal is to be a future FDA leader or executive. This wonderful opportunity is open to individuals interested in developing and improving their leadership skills and developing new insights into the Agency's overall mission.

Participants are required to prepare an individual development plan (IDP) under the guidance of a mentor. They must complete a 60-day assignment outside their home organization; a 60-day assignment in a supervisory role (for non-supervisors); and a 30-day assignment in the field for headquarters employees or at headquarters for field employees. In addition, they must complete three shadowing assignments of at least three days each with FDA senior managers for the purpose of observing different management styles. Last, participants are required to complete FDA's Leadership Skills I and II courses, both of which are 5-day residential courses. Don't forget the paperwork! Participants are requested to submit appraisals from assignment supervisors and participant evaluations within two weeks after the completion of each assignment.

I recently completed the program and found myself participating in a whirlwind of exciting challenges. The program allowed me to engage in developmental assignments within and outside of the Agency. For example, I honed my supervisory skills in the Baltimore District while acting as District Director and Director of the Investigations and Compliance Branches. I also rotated in the Offices of Legislation and Women's Health. I never dreamed that I would work with the Food Safety Unit of the World Health Organization and shadow with Dr. Bernard Schwetz, Acting Principal Deputy Commissioner.

This last year has allowed me to reach my goals, take risks, and learn more about myself. Now, with a greater knowledge base, enhanced professional growth and extended confidence, I am ready to assume a leadership position. More importantly, I am grateful to the Agency and to the Center for this once in a lifetime opportunity.

Dr. Brown-Reid is a Veterinary Medical Officer in CVM's Office of New Animal Drug Evaluation. □

TAKING OUR MESSAGE ON THE ROAD: THE CVM EXHIBIT PROGRAM

by Joanne M. Kla

The Center for Veterinary Medicine's (CVM) exhibit program serves as a valuable tool to get our message out to our stakeholders: the veterinary medical community, practitioner specialty groups, animal producers, animal scientists, animal producer groups, and the regulated industry. Although CVM has had an exhibit program for many years, it has recently expanded under the Food Safety Initiative (FSI). The exhibit is an important educational component of FSI. Here is some information about the exhibit program and recent activities.

What does the exhibit look like?

CVM's exhibit consists of backdrop area that is 10 feet wide by 8 feet high where we mount posters and pictures related to the theme of the meeting and CVM's mission. For example, we have a large selection of photographs of animal species served by CVM's regulatory authority as well as photographs of our state-of-the-art animal research facility. We also add posters on specific topics such as antimicrobial resistance. We use the exhibit as an information dissemination tool and a recruitment tool.

What does the exhibit do?

The purpose of the CVM exhibit program is to get CVM's message out to our stakeholders, with an opportunity for person-to-person interaction. Generally, the CVM exhibit will carry a theme message directed at the meeting participants geared to topics considered at the meeting, such as Antimicrobial Resistance, Bovine Spongiform Encephalopathy (BSE). We frequently bring a laptop computer along with the exhibit in order to offer "guided tours" of the CVM Website and inform people of the variety of information available on this site. CVM publications available at the booth are often a big draw. Information on CVM's facilities and on-going activities are usually quite popular, especially materials about employment opportunities and summer internship programs.

Vash Klein and Linda Grassie staff CVM'S exhibit at AVMA Convention, Boston, MA.

Where have we gone?

In the last year, we took our exhibit to four large national meetings:

- **World Dairy Expo** held in Madison, WI, October 4-8, 2000. The 69,575 attendees included 3,532 international guests from 85 countries.

(Continued, next page)

AG-TERRORISM WORKING GROUP

by Isabel Arrington, Ph.D., D.V.M.

Recent events have focused attention on terrorist incidents aimed at the civilian population. An agricultural attack involving biologicals or chemicals could be surreptitious and thus difficult and time-consuming to detect. Symptoms might not occur among victims for days or weeks and those initially presenting themselves to physicians and clinics might be geographically dispersed. A strong public health network would be needed to piece together early reports and determine quickly what had happened. Similarly, if animal feeds were contaminated by acts of terrorism, the human population could be potentially affected by consuming resulting residues in meat products, direct contact with contaminated pet foods in the home or contact with certain animal disease conditions caused by feed contaminants.

I was hired by CVM to be the point person on agricultural-terrorism for the Center and to lead CVM's working group on those activities. Currently, CVM is in the process of organizing the work group to formalize plans and attending many meetings with CFSAN and other Agencies to keep abreast of the latest ideas in agricultural and bioterrorism relating to foods. It is expected that most of CVM's activities will be about improving communication and coordination among State and Federal labs that deal with animal feeds and providing scientific expertise in feed contamination issues. I previously worked at USDA, Food Safety and Inspection Service in Field Operations, first as an Inspector in Charge, and later as a technical expert at headquarters and in the Technical Service Center, Omaha, NE.

Dr. Arrington is a Veterinary Medical Officer in CVM's Division of Animal Feeds. □

TAKING OUR MESSAGE ON THE ROAD . . . (Continued)

- **International Poultry Expo,** held in Atlanta, GA**,** January 16-19, 2001, drew over 22,000 participants, with several thousand international attendees.
- **American Veterinary Medical Association,** held in Boston, MA, July 14-17, 2001, had 7,496 participants (3,293 veterinarians, 308 veterinary students, 1,267 exhibitors, 1,804 guests)
- **International Animal Agriculture and Food Science Conference,** held in Indianapolis, IN, July 24-27, 2001, was attended by 4,481 people from over 65 countries.

What kind of literature do we distribute?

Informational booklets and brochures are distributed such as:

– *FDA Veterinarian*
– *Judicious Use of Antimicrobials for Poultry Veterinarians*
– *Judicious Use of Antimicrobials for Dairy Veterinarians*
– *Judicious Use of Antimicrobials for Swine Veterinarians*
– *Judicious Use of Antimicrobials for Beef Veterinarians*
– *National Antimicrobial Resistance Monitoring System – Enteric Bacteria*
– *Office of Research Informational Brochure*
– *Employment Opportunities*
– *How to Apply for a Job in the Federal Government*
– *CVM Pharmacovigilance Program*
– *FDA and the Veterinarian*
– *Summer Internship Brochure*

What kinds of questions do we answer?

We receive inquiries from university professors and students, animal producers, veterinary practitioners, and State and local government officials about the products we regulate, the drug approval process, extra-label use, diseases of concern (such as BSE), as well as general questions about FDA. We frequently get questions from the foreign countries about FDA regulations for new products and imports. Many of these questions we can answer directly. For others we find an answer by using our Website or directing people where to look for this information on the CVM or FDA Website.

These badge stickers are distributed to all visitors to the CVM exhibit.

Many visitors express interest in employment with CVM (at this year's AVMA meeting approximately 25 percent of the inquiries at the booth were about employment opportunities). Many of these individuals expressed an interest in public health/epidemiology. Other frequent topics of interest are the Judicious Use materials and antimicrobial resistance in general, how to go about having a product approved by CVM, medical devices, aquaculture, where to find things on our Home Page, etc.

So, the next time you see our exhibit at a meeting you are attending, be sure to stop by and visit!

Joanne Kla is a Consumer Safety Officer in CVM's Communications Staff. □

OFFICE OF RESEARCH OFFERS WORKSHOP

by Shabbir Simjee, Ph.D.

The Division of Animal and Food Microbiology (DAFM) based at CVM's Office of Research (OR), Laurel, MD recently repeated a workshop on Microbiology and Molecular Biology due to an overwhelming response to the first workshop held in April, 2001. This workshop was open to all CVM employees and it was aimed at bringing everyone up to scratch with the latest techniques available. In addition it provided an opportunity for those employees that no longer do laboratory work to get some hands-on experience. The course also served as a refresher for those that have become somewhat rusty on methods and techniques.

The workshop consisted of a series of lectures and hands-on experience. In some cases, where hands-on is not practical, demonstrations were performed. The DAFM team has a diverse range of expertise ranging from basic microbiology to sophisticated state-of-the-art molecular biology expertise. As a result of all these skills, all members of the DAFM team took part in the organization, participation and demonstrations of the various aspects of the two-day course. The participants were divided into two teams, the micro team and the molecular team. Each team completed two days of seminars and hands-on work, concluding with a final Q&A session.

Subjects covered by the micro team included:

Isolation of *Salmonella*, *Enterococcus*, *Campylobacter* from retail meat samples, confirming bacterial identity by VITEK, Gen probe and enzyme immunoassay, antibiotic susceptibility testing by agar dilution, Kirby-Bauer, E-Test and broth microdilution.

Subjects covered by the molecular team included:

Introduction to DNA, the polymerase chain reaction, DNA sequencing, pulsed field gel electrophoresis, gene exchange by conjugation and concluding with a presentation on DNA sequence aliments, translations and looking for mutations.

Eighteen members from various units of CVM attended the fall course held October 3-4, 2001.

Dr. Shabbir Simjee is a Microbiologist in CVM's Office of Research. □

CVM HOSTS FIELD COMMITTEE

by Ballard H. Graham

The FDA/ORA/CVM Field Committee met on August 20-22, 2001, at the Hilton Hotel, Gaithersburg, MD. Current members of the committee are: Ballard H. Graham, Atlanta District Director, Chair; Brenda Holman, Pacific Regional Food and Drug Director, Advisor; Thomas (Tom) Gardine, Philadelphia District Director, Vice Chair; James (Jim) Rahto, Minneapolis District Director, Jerome (Jerry) Woyshner, New York District Director, Gayle Lancette, Director, Southeast Regional Lab., Austin (Rick) Long, Director, Pacific Regional Lab., Northwest, and Darrell Lee, Director of Compliance, San Francisco District.

Members of the CVM Field Committee, left to right: Darrell Lee, Jerome Woyshner, Brenda Holman, Thomas Gardine, Gayle Lancette, Ballard Graham, James Rahto, and Rick Long.

There are five FDA/ORA Program Field Committees, including the Drug, Device, Food, Biologics, and CVM Committees. Their purpose is to assist in managing the Office of Regulatory Affairs (ORA) organization and its implementation of Agency programs. This includes, but is not limited to, serving as the principal contact for ORA (Field and Headquarters) and Centers on matters relating to the specific program area. Field Committees are the primary liaison between ORA and the Centers on general program matters. As such, they seek input from ORA components on Center proposals, programs, and initiatives in order to formulate an "institutional" ORA position. Similarly, they also seek input from Centers on ORA initiatives.

The Field Committee reviews and clears, with appropriate ORA input, assignments, compliance programs, circulars, and changes issued by the Center to the Field, consistent with current Field Management Directives. They also coordinate and participate with the Center in developing program implementation goals, strategies, procedures, strategic enforcement initiatives, problem solving, and evaluation measures necessary to ensure effective execution of the Agency's responsibilities.

CVM management participants in the meeting included: Dr. Stephen Sundlof, Director, CVM; Dr. Linda Tollefson, Deputy Director, CVM, Dr. Daniel McChesney, Acting Director, Division of Surveillance and Compliance; and Glo Dunnavan, Director, Division of Compliance.

Others present at the meeting included staff members from the Office of Enforcement (OE), Office of Regional Operations (ORO), Division of Federal State Relations (DFSR), Division of Emergency Investigational Operations (DEIO), Division of Field Science (DFS), Office of Resource Management (ORM), Division of Planning Evaluation Management (DPEM); and the President of the Association of American Feed Control Officials. (John Breitsman)

This two-and-a-half-day meeting focused on the Agency's Bovine Spongiform Encephalopathy (BSE) surveillance and enforcement policy activities. Dr. Mac Lumpkin, Senior Medical Advisor to the Acting Commissioner, provided an Agency overview of the HHS and FDA BSE and TSE (Transmissible Spongiform Encephalopathies) Action Plans.

Dr. Steven Solomon, Deputy Director, Office of Regional Operations (ORO), provided an ORA perspective with respect to BSE accomplishments and enforcement activities.

Glo Dunnavan, Director, Division of Compliance, provided a CVM perspective with respect to BSE resources that have been and will continue to be made available to maintain surveillance and, as needed, enforcement in an effort to maintain full oversight.

Dr. Sundlof provided a presentation on the "FDA Leadership Council" concerning its mission with respect to ORA/Center(s) working together to achieve maximum efficiency regarding the utilization of Agency resources.

Other pertinent topics and presentations made during the meeting included: The New BSE Checklist and Database Form, the Voluntary Self Inspection Program (VSIP), Tissue Residue Surveillance and Enforcement Strategies, Vet Drug Pharmacy Compounding, and Cloned Milk and Meat. In addition, a presentation on "Procedures for Reporting and Responding to Congressional Inquiries" was provided by ORA's Executive Secretariat, Marie Urban.

A couple of celebrations were in order as the Committee congratulated Dr. Linda Tollefson on her promotion to Rear Admiral, and Jerry Woyshner on his recent appointment as New York District Director.

The meeting generated several action items for the committee as well as CVM, DFSR, ORO, DPEM, *et al*. The action items from this meeting will be revisited by the committee during subsequent committee conference calls and at the next committee meeting, tentatively planned for early 2002.

Ballard Graham is the Director of FDA's Atlanta District Office, and Chairman of the CVM Veterinary Field Committee. □

10 PRESIDENTIAL MANAGEMENT INTERN PROGRAM AT CVM

by Chris Middendorf, M.S.

On the third floor in the 7500 Building at Standish Place, amongst the staff of veterinarians in the Office of New Animal Drug Evaluation (ONADE), in the Division of Therapeutic Drugs for Non-Food Animals, a young intern works at updating information on Investigational New Animal Drugs (INADs). I am a Presidential Management Intern or PMI and I am now three months into a six-month rotation to CVM from the Office of the Commissioner. I spent three months at CVM's aquaculture facility in Laurel, MD prior to joining ONADE in mid-August. The PMI program has generated a lot of interest throughout CVM, as this program is relatively new to CVM.

The PMI program is designed to attract qualified individuals from a wide variety of academic disciplines to a career in the Federal Government. The PMI program provides a continuing source of graduate students to Federal Agencies who will help meet the future challenges of public service. The program's duration for an individual is two years, and at the end of the program the Agency has the option of converting the PMI to a regular full-time employee. During those two years, PMIs are given detailed training for their individual jobs and broad management training with a multitude of practical applications.

Interns under this program enter the Federal service and may be appointed without testing or further competition using a Direct Hire Authority. They are hired at the GS-9 level with all benefits available to status employees. They earn annual promotions and are converted at the GS-12 level when they complete the program. Rotations are an integral part of the PMI curriculum and vary between agencies and between Centers. For me, a six-month rotation to CVM is providing a broad view of the Center's operations.

Admission to the PMI program is competitive with about 1,800 students competing for 400 positions. Applying to the PMI program is also a one-time opportunity. Students may only apply in the academic year they are scheduled to graduate and must be nominated by their schools. Successful completion of their graduate program is required in order for students to enter on duty at a Federal agency. Currently FDA has nine of these "Elite" Presidential Interns on board or scheduled to come on board before the end of the year.

At first the program was limited to applicants from public management and administration graduate majors. However, the government realized there was a need for graduates with more diverse academic backgrounds and in the early 1980's the program was expanded to include nearly all graduate areas of study.

I received my M.S. in Animal Science from Auburn University, and I learned about the PMI program by accident. At the time, I was President of the Graduate Student Council at Auburn and was given information about the PMI program to disseminate to graduate students at the University. The application was very thorough. I was required to list all subject matters that I had taken for college credit and how many hours I took. I was also required to list any skills that I possessed such as foreign language proficiency.

That winter the applicants received letters stating that they were to report to a regional Federal Assessment Center. In my case it was the Federal building in downtown Atlanta. My experience was nearly identical to the thousand or so applicants that OPM would assess for the PMI class of 2000. The testing began early in the morning. When I arrived, I was ushered into a room where other people were waiting; this would be my assessment group. The assessment consisted of a writing exam, an impromptu speech, and a group exercise. Assessment panels were comprised of senior government administrators who evaluate the participants' ability to communicate and work within a group. Those students who were selected as PMI finalists are notified mid-March and invited to a job fair in Washington, DC, the second week of April.

At the PMI job fair I began to understand how lucky I was to be a PMI finalist. It appeared that every Agency in the Federal government was represented at the job fair and they all had jobs to offer on the spot. PMI finalists can be recruited into an agency through a Direct Hire Authority that eliminates the traditional long hiring procedures that agencies routinely use. The job fair is a seller's market with PMIs receiving multiple job offers. I received job offers from the Federal Aviation Agency, Social Security, and the Department of the Army, but I held out until I got an offer from FDA. Experiences such as this were common place at the job fair as Federal Agencies try to replenish a professional work force that edges closer to retirement each year.

Greg Chambers, an MPA graduate of The University of Colorado, describes his job fair experience as similar to mine and other PMI finalists. **"**The Job Fair was fast paced and overwhelming for me. I was exhausted at the end of each day due to the non-stop scheduling of interviews, off-site interviews and interviews at the actual Job Fair. At the fair I received offers for positions that matched my background probably because I primarily targeted HHS agencies and those involved with health care." Greg was heavily recruited by twelve different offices/ agencies before eventually accepting an offer as a program analyst in FDA's Office of Planning.

"PMIs are appealing to an agency because they are well screened," explains Margie Dexter, one of the FDA recruiters at the job fair. "They have advanced degrees, high GPAs, and most are high achievers. These graduates have selected the Federal service as their employer of choice". The fact that PMIs are individuals who want to work for the government is encouraging to Federal

(Continued, next page)

managers who are facing what the General Accounting Office calls a "human capital crisis".

Once a PMI finalist has been hired by an agency, he or she attends a PMI orientation presented by OPM at the Management Training Facility in Shepherdstown, WV. During the 3-day orientation the PMIs are introduced to life in the Federal service and are placed into Career Development Groups (CDGs). CDGs serve a professional and social role. Members of CDGs plan a two-year course of professional development for the group with the help of a senior administrator assigned as an advisor. Members construct individual development plans that are specific for their career goals. The CDGs also plan social events to allow networking between the PMIs. Social events allow PMIs to meet many people with diverse educational backgrounds and provide them with contacts throughout the Federal Government. The PMI program fosters an "esprit de corps" that doesn't end after the participants have graduated from the program. There is a PMI alumni association that keeps networks alive and provides a common thread for this group of Federal employees throughout their careers.

I am glad I applied to the PMI program through my University. The PMI program has provided me with great learning opportunities, and I am able to significantly contribute to the Agency. I heartily recommend the program to managers and supervisors and to students as well. It is a good example of a program that is working well.

Chris Middendorf is a Presidential Management Intern in CVM's Office of New Animal Drug Evaluation. □

FDA HOLDS PUBLIC HEARING ON RUMINANT FEED (BSE) RULES

The Food and Drug Administration (FDA) held a public hearing October 30, 2001, to solicit information and views on its present animal feeding regulation "Animal Proteins Prohibited in Ruminant Feed" – *Code of Federal Regulations*, Title 21, Part 589.2000 (*http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfr589_01.html*). The purpose of the rule is to help prevent the establishment and amplification of bovine spongiform encephalopathy (BSE) in U.S. cattle herds through feed and thereby help minimize any risks from BSE to animal or human health.

FDA recognizes that new information has emerged on BSE and variant Creutzfeldt-Jakob Disease (vCJD) since the rule went into effect in 1997. Therefore, FDA is requesting information and views from individuals and organizations on the present rule and whether changes in the rule or other additional measures are necessary. The Agency is 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.

Written comments regarding this issue are welcome at anytime; however, the official record of the hearing will remain open to receive written comments until November 21, 2001. Individuals and organizations wishing to submit written comments on these issues should submit their written comments to the Dockets Management Branch, HFA-305, Food and Drug Administration 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Individuals may submit one copy of their comments; others are requested to submit two copies of their comments. Those submitting written comments should identify their comments with Docket No. 01N-0423. To submit electronic comments go to *http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm*.

Additional information about the hearing is available in the October 5, 2001, *Federal Register (http://www.fda.gov/OHRMS/DOCKETS/98fr/100501b.htm)*. □

BSE INSPECTION CHECKLIST AVAILABLE ON THE CVM HOME PAGE

FDA's Center for Veterinary Medicine (CVM) has made available the Bovine Spongiform Encephalopathy (BSE) Inspection Checklist on the Center's Home Page on the Internet at: *http://www.fda.gov/cvm/forms/forms.html*. This checklist is to be used by Federal and State inspectors to determine compliance with FDA's ruminant feed (BSE) regulations, *Code of Federal Regulations*, Title 21, Part 589.2000 (*http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfr589_01.html*.)

This rule prohibits the use of most mammalian protein in feeds for ruminant animals and was implemented to prevent the establishment and amplification of BSE through feed in the United States. The rule became effective on August 4, 1997. Inspections of more than 10,000 renderers, feed mills, ruminant feeders, and others (such as protein blenders) have been conducted to determine compliance with the BSE feed regulations. The majority of these inspections (around 80%) were conducted by State officials and the remainder by FDA. A checklist has been used to record information on the compliance with the rules. The checklist that is being made available on the CVM Home Page is a revised version intended for use in future inspections.

Questions or comments about the checklist may be directed to Dr. Neal Bataller in CVM's Division of Compliance at: *Nbatalle@cvm.fda.gov*, 301-827-3353.

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by Karen A. Kandra

The following firms/individuals received warning letters for offering animals for slaughter that contained illegal drug residues:

- James Schairer, President, James Schairer Farms, Inc., Birnamwood, WI
- Thomas E. Longhenry, Owner, Longhenry Farms, Glencoe, MN
- Thomas Paskewitz, Co-owner, Paskewitz Cattle Co., Vesta, MN
- Hugh C. Cox, Owner, Hugh Cox Livestock, Calhoun, GA

These violations involved illegal residues of gentamicin in a cow; tilmicosin and phenylbutazone in a dairy cow; and, penicillin in dairy cows.

A warning letter was issued to the following firms for violations related to 21 CFR Part 589.2000 – Animal Proteins Prohibited in Ruminant Feed. This regulation is intended to prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE).

- Barrie or James Wilcox, Co-Presidents, Wilcox Farms, Inc., Roy, WA
- William W. Himmelspach, Owner, Tualatin, OR
- Charles A. Holdren, CEO/President, Agri-Mark Farmers Co-op, Inc.
- Mark W. Roesner, Owner/President, Copley Feed & Supply, Copley, OH
- Barbara J. Hinton, President, The Hyland Co., Inc., Ashland, KY
- Terry R. Renner, President, F.W. Renner & Sons, Inc., Canton, OH

Violations included failure to establish a written system, including clean-out and flushing procedures to avoid commingling and cross-contamination of common equipment; failure to separate the receipt, processing, and storage of the product containing prohibited material from non-prohibited material; failure to maintain records sufficient to track the materials throughout the receipt, processing, and distribution of products; failure to label products with the required cautionary statement "Do No Feed to Cattle or Other Ruminants."

Marvin L. Goldberg, President, Equirace Health and Speed Products, Washington, PA, received a warning letter for distributing prescription veterinary and human drugs to lay persons without a lawful order from a licensed veterinarian who has a valid veterinarian-client-patient relationship with his/her customers. In addition, certain prescription veterinary and human drugs offered for sale by Equirace are adulterated within the meaning of Section 501(a)(5) of the Act in that they are new animal drugs that are unsafe within the meaning of Section 512(a)(1)(A) because there are no approved applications filed pursuant to Section 512(b) for their use in horses.

The following drugs are not approved for use in horses: methocarbamol tablets; Bactrim (sulfamethoxazole/trimethoprim) tablets; isoxsuprine tablets; Baytril (enrofloxacin) injection; and Naquasone (dexamethasone/trichlormethiazide) bolus. Likewise, these drugs are misbranded within the meaning of Section 502(f)(1) of the Act in that their labeling does not contain adequate directions for use of these drugs in horses.

The inspection revealed that a partner at Equirace, Franklin Pellegrini, D.V.M., is a licensed veterinarian, however, he does not have a valid veterinarian-client-patient relationship with any of Equirace's customers. Further, the inspection found that Dr. Pellegrini's role at Equirace is not to dispense medication in his capacity as a licensed veterinarian, but to act as a consultant should a customer have questions about the drugs he or she is purchasing.

John W. Peters, General Manager, Thomas Products LLC, Madera, CA, received a warning letter for significant deviations from Current Good Manufacturing Practice (CGMP) regulations for medicated feeds. Violations included failure to perform three assays for Amprol 25% (amprolium), failure to sequence, flush, or physically clean the manufacturing and delivery equipment between batches of medicated feed to ensure that cross-contamination does not occur; failure to maintain a daily theoretical drug inventory of Type A medicated articles; and, failure to provide adequate directions for use for medicated feeds sold by the firm.

John Swisher, Owner/CEO, United Feeds, Inc., Sheridan, IN, received a warning letter for selling and shipping a Category II Type A Medicated Article to a customer lacking a valid FDA Medicated Feed Mill License. In addition, several deviations from CGMP's were found, such as, failure to perform a follow-up investigation of an out-of-limits assay, i.e., superpotent penicillin; failure to clean scoops used to handle Medicated Articles; failure to prevent dust on drug component bags; and, heavy accumulation of dust on floor, bulk containers and shelves in the component storage and mix areas. □

Photo by Keith Weller

2002 FDA SCIENCE FORUM

The 2002 FDA Science Forum, titled "FDA: Building a Multidisciplinary Foundation," will be held February 20-21, in the Washington Convention Center, Washington, DC. The program will focus on how FDA's many different scientific and regulatory disciplines support the public health programs of the Agency. The first day will discuss the importance of research, policy development, and review in public policy decision-making. The second day will emphasize how the principles of public health surveillance, from both the domestic and global prospective, can be applied to FDA's science issues.

An integral part of this year's science forum will be interactive breakout sessions that discuss in depth the importance of research, review, policy and regulation in the development of FDA's public health policies. The break-out session topics will include bioengineered foods, botanicals, bioterrorism, antibiotic resistance, children's health issues, tissue engineering, genomics, and bovine spongiform encephalopathy. The break-out sessions on the first day will focus on the importance of sound research and review in responding to public health issues. The break out sessions on the second day will focus on impact of policy and regulation on public health programs.

The FDA Science Forum is open to all those interested in learning more about FDA's multi-faceted scientific approach to many diverse public health issues. Information about the program and registration can be found at FDA's web page @ *www.fda.gov* or by contacting Dr. Suzanne Fitzpatrick by e-mail at *sfitzpat@oc.fda.gov* or by phone at 301-827-4591.

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FINAL GUIDANCE AVAILABLE ON FUMONISIN LEVELS IN HUMAN FOOD AND ANIMAL FEEDS

FDA announced the availability of a final guidance document entitled "Guidance for Industry: Fumonisin Levels in Human Foods and Animal Feeds" in the November 9, 2001, *Federal Register*. The purpose of the guidance is to identify for the industry fumonisin levels that FDA considers adequate to protect human and animal health and that are achievable in human foods and animal feeds with the use of good agricultural and good manufacturing practices.

FDA considers this guidance to be a prudent public health measure during the development of a long-term risk management policy and program by the agency for the control of fumonisins in human foods and animal feeds. The Agency is also announcing the availability of the final supporting documents entitled "Background Paper in Support of Fumonisin Levels in Corn and Corn Products Intended for Human Consumption," and "Background Paper in Support of Fumonisin Levels in Animal Feed."

The guidance document is on the FDA Home Page on the Internet at: *http://www.fda.gov/OHRMS/DOCKETS/98fr/001277gd.pdf*. Single copies of the guidance may be obtained by writing to the Communications Staff, FDA/Center for Veterinary Medicine, 7519 Standish Place, HFV-12, Rockville, MD 20855, 301-827-3800. Please send one self-addressed adhesive label to assist in processing your request. The "Background Paper in Support of Fumonisin Levels in Corn and Corn Products Intended for Human Consumption" and "Background Paper in Support of Fumonisin Levels in Animal Feed" are available for public viewing at the FDA Dockets Management Branch (5630 Fishers Lane, Room 1061, Rockville, MD 20852) between 9 a.m. and 4 p.m. Monday through Friday. Electronic copies are available on the FDA/CVM Home Page at: *http://www.fda.gov/cvm/index/other/fumonisin.htm*

Written or electronic comments concerning the final guidance and the final supporting documents may be submitted at any time to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Electronic comments may be submitted to *http://www.accessdata.fda.gov/scripts/oc/dockets/commentdocket.cfm*.

Additional information may be found in the November 9, 2001, *Federal Register* at: *http://www.fda.gov/OHRMS/DOCKETS/98fr/110901c.htm* or from Dr. Randall Lovell, Center for Veterinary Medicine (HFV-222), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 301-827-0176.

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Company	*Generic and (Brand) Names*	*Indications*	*Routes/Remarks*
Bayer Corp., Agriculture Division, Animal Health (NADA 141-188)	Ponazuril (Marquis™) Rx	Horses. For the treatment of equine protozoal myeloencephalitis.	**ORAL:** The NADA provides for veterinary prescription use of ponazuril paste for the treatment of equine protozoal myeloencephalitis caused by *Sarcocystis neurona*. Use daily for 28 days. Not for use in horses intended for food. *Federal Register* 08/21/01


Photo by Scott Bauer

Alpharma, Inc. (NADA 141-179)	Lasalocid (Avatec®), Bacitracin Methylene Disalicylate (BMD®)	Turkeys. For the prevention of coccidiosis, for increased rate of weight gain, and for improved feed efficiency.	**MEDICATED FEED:** The NADA provides for use of approved single-ingredient lasalocid and bacitracin methylene disalicylate Type A medicated articles to make two-way combination drug Type C medicated feeds. The medicated feeds are used for prevention of coccidiosis caused by *Eimeria meleagrimitis, E. gallopavonis, E. adenoeides*. *Federal Register* 09/05/01 □


Photo by Scott Bauer

Company	*Generic and (Brand) Names*	*Indications*	*Routes/Remarks*
Pfizer, Inc. (NADA 141-151)	Marbofloxacin (Zeniquin™) Rx	Cats. For the treatment of infections associated with bacteria that are susceptible to marbofloxacin.	**ORAL:** The supplement provides for the addition of cats to product indications which originally stated for use in dogs. *Federal Register* 09/05/01
Fort Dodge Animal Health (NADA 141-099)	Moxidectin (Cydectin® 0.5% Pour-On for Cattle)	Cattle. For the treatment and control of roundworms.	**TOPICAL:** The supplement provides for use of the Pour-on for Beef and Dairy Cattle at 500 micrograms moxidectin per kilogram of body weight for treatment and control of infections of additional life stages and species of gastrointestinal roundworms. *Federal Register* 09/05/01
Alpharma, Inc. (NADA 96-298)	Lasalocid (Bovatec®)	Pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers). For increased rate of weight gain.	**MEDICATED FEED:** The supplement provides for an increased daily dosage of lasalocid in pasture cattle. *Federal Register* 09/11/01

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Photo by Keith Weller

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