# FDA VETERINARIAN

Center for Veterinary Medicine

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# FDA Publishes "Indexing" Final Rule Under MUMS Act

The Food and Drug Administration has published the final rule to implement the Legally Marketed Unapproved New Animal Drug Index (the Index) authorized by the Minor Use and Minor Species Animal Health Act (MUMS Act) of 2004.

This rule provides an alternative means for companies to market veterinary drugs for uses that are not amenable to the full FDA approval process, such as products for species too varied or inherently valuable to be used in the studies usually conducted to establish a product's effectiveness and safety. In short, these will be products for use in animals like ornamental fish, pet birds, laboratory animals, pocket pets, endangered species, and zoo animals.

Indexing will only be an option for species that are not used to produce food, with the exception of certain early life stages such as some fish eggs.

The Indexing final rule was published in the December 6, 2007, *Federal Register*, and it becomes effective on February 19, 2008. FDA will not be able to accept submissions for Indexing drugs until the final rule becomes effective.

The Indexing process will include three major steps. First, upon a sponsor's request, FDA will evaluate the eligibility of a new animal drug to be considered for the list. Second, the sponsor will ask FDA to concur with its expert panel selection. This panel of experts will review all of the drug's available target animal safety and effectiveness data. Third, the panel's findings will be presented as a report to FDA so the Agency can determine whether the drug should be included in the Index. Drugs successfully reviewed under the Indexing rule are placed in a public index of unapproved drugs that can be legally marketed.

The rule was first proposed in August 2006. It was open for comments a total of 120 days. FDA made some changes to the final rule based on those comments,

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# Steps Taken To Avert Shortage of Injectable Drug for Pigs

*by Walt D. Osborne, M.S., J.D., Assistant Editor*

Because of the shortage of the drug, iron dextran, the Food and Drug Administration is working with sponsors to exercise discretion on a case-by-case basis over the importation into the United States of the 200 mg/mL iron dextran from foreign sources.

Injectable iron dextran is approved by FDA for the prevention and treatment of iron deficiency anemia in baby pigs. Because injectable iron dextran is considered a medically necessary drug for this indication, and a shortage could result in undue animal suffering and disruption in the swine industry, FDA is working with sponsors to make adequate supplies of the drug available to treat newborn pigs.

### *Iron is essential for baby pigs*

Iron administration within 1 to 3 days after a pig's birth is essential for preventing iron deficiency or anemia. Newborn pigs are very vulnerable to iron deficiency, more so than many animals, for the following reasons:

(1) Newborn pigs are born with only moderate stores of iron, mostly in the liver, but only enough to sustain their hemoglobin for 3 to 4 days.

(2) Newborn pigs grow at an extremely fast rate, quadrupling their body weight in 3 to 4 weeks. Therefore,

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

# FDA Publishes "Indexing" Final Rule *(Continued)*

including changes to the rules concerning scheduling conferences, reviewing the written report of such conferences, and selecting appropriate members for the review panel.

The rule implements Section 572 of the Federal Food, Drug, and Cosmetic Act, entitled "Index of Legally Marketed Unapproved New Animal Drugs for Minor Species." The regulations describe the administrative procedures and criteria for listing a drug in the Index.

The Indexing regulations were designed to be a means by which companies can legally market veterinary drugs for certain minor species without going through the long and expensive new animal drug approval process.

The MUMS Act, of which Indexing is a part, was developed to provide new ways to bring products to market for the treatment of rare diseases in major species (cows, pigs, chickens, turkeys, horses, cats, and dogs) and to treat all other animal species (minor species). The MUMS Act was created because sponsors were developing or seeking approval for few drugs for minor uses or minor species due to limited markets or, in some cases, the difficulty in finding means to generate data necessary for approval.

The MUMS Act has two other key provisions already in effect:

- **Designation** makes drugs eligible for 7 years of exclusive marketing rights starting on the day of approval or conditional approval. In addition, when funds are appropriated, FDA will be able to provide grants to defray costs of qualified safety and effectiveness testing as well as manufacturing expenses incurred in the development of designated new animal drugs. The final rule regarding designation can be seen on the CVM Web site at *http://www.fda.gov/OHRMS/DOCKETS/98fr/E7-14444.pdf*. CVM also provides the list of designated drugs at *http://www.fda.gov/cvm/MumsDesigList.htm*.
- **Conditional approval** allows a drug sponsor to make the drug available before collecting full effectiveness data, but after proving that the drug is safe and meets all other approval requirements. The sponsor can keep the product on the market for up to 5 years, through annual renewals, while collecting the needed effectiveness data. In April 2007, CVM granted the first conditional approval to a drug to treat columnaris disease in catfish.

### Additional staff member

CVM has also announced that Dr. Joan Gotthardt will join the Center's Office of Minor Use and Minor Species in February 2008 to direct the implementation of the Indexing provisions of the MUMS Act.

Dr. Gotthardt has been with the Center since 1995. For the past 5 years, Dr. Gotthardt has served as Director of the Division of Therapeutic Drugs for Food Animals in CVM's Office of New Animal Drug Evaluation.

She received her bachelor's degree in Animal Science from the University of Maryland and her Doctorate of Veterinary Medicine from the Virginia Maryland Regional College of Veterinary Medicine.

Dr. Gotthardt joins Dr. Bernadette Dunham, who serves as Director of the Office, as well as Deputy Center Director; Dr. Meg Oeller, who handles drug designation and serves as the FDA liaison to the USDA's minor species program, NRSP-7; and Dr. Andrew Beaulieu, immediate past Office Director, now assisting the Office as a special consultant.

## Indexing Implementation Dates

Indexing final rule becomes effective **February 19, 2008. CVM can accept requests for eligibility on that date and not before**.

The Final Rule was published December 6, 2007.

# Steps Taken To Avert Shortage… *(Cont.)*

muscle mass and blood volume increase rapidly, and the hemoglobin quickly becomes diluted in the blood.

(3) Milk is the only food consumed by baby pigs during the first few weeks after birth, and milk is not a good source of iron; a quart of milk contains only about 1 mg of iron. Pigs require 7 to 8 mg of iron every day.

(4) Pigs are raised in an environment where they cannot get iron from other sources (e.g., nuzzling in the soil) because the floors are concrete, steel, rubber, or plastic.

All of this stated, it is important to note that no more than 200 mg of iron should be given to pigs. Higher levels of iron encourage systemic bacterial growth and can lead to diarrhea and possible toxicity.

### FDA's imported drug restrictions

Section 301 of the Federal Food, Drug, and Cosmetic Act prohibits the

*(Continued, next page)*

*FDA VETERINARIAN*

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# CVM, AAFCO Sign Agreement on Feed Ingredient Listing

*by Jon F. Scheid, Editor*

The Food and Drug Administration's Center for Veterinary Medicine has signed a Memorandum of Understanding (MOU) with the Association of American Feed Control Officials (AAFCO) that allows FDA to formally recognize AAFCO's process to develop a list of feed ingredients and defines the role FDA can play in deciding on the suitability of feed ingredients offered for addition to AAFCO's list.

FDA's formal recognition of the AAFCO list is one of the specific recommendations made in a "Framework Document" drafted by FDA's Animal Feed Safety System (AFSS) Team. FDA created the ad hoc AFSS Team 4 years ago to develop ways to modernize the feed safety system in the United States. The Team has identified "gaps" in the current animal feed regulatory structure (including the fact that FDA regulations do not include a complete list of suitable feed ingredients) and offers recommendations for closing the gaps.

AAFCO is a voluntary organization comprised largely of regulatory officials who have responsibility for enforcing their State's laws and regulations concerning the safety of animal feeds. It is made up of members from each State in the United States and Puerto Rico, as well as from FDA, the U.S. Department of Agriculture, and the governments of Costa Rica and Canada.

A basic goal of AAFCO is to provide the means for ensuring the development and implementation of equitable laws, regulations, standards, definitions, and enforcement policies for regulating animal feed. AAFCO is an advisory group and has no enforcement authority. The State regulatory agencies that make up the membership of AAFCO carry out enforcement in their State if necessary.

AAFCO publishes an annual *Official Publication (OP)* that includes a list of all ingredients AAFCO has reviewed and found suitable for use in animal feeds. The *OP* also contains cross-references to certain sections of the Code of Federal Regulations that list approved food additives and ingredients that are Generally Recognized as Safe for use in animal feed. The *OP* is considered to contain the most current and extensive list of common or usual ingredient names. FDA has informally cited the *OP's* ingredient list and has acted as AAFCO's scientific advisor in reviewing petitions for the addition of ingredients to the list or for changes in the ingredient definitions. However, although the *OP* ingredient list does have the force of law in those States that adopt it, it does not carry the force of law for FDA.

Under the MOU, CVM assigns scientists to work with AAFCO in reviewing petitions for new feed ingredients or for modifications to existing ingredient definitions. Also, before it adopts a new feed ingredient definition or amends an existing one, AAFCO will ask CVM for advice and a letter of concurrence. In addition, the MOU requires AAFCO to remove a definition from its *OP* if FDA provides convincing scientific evidence that the ingredient is no longer suitable for its intended purpose.

The MOU went into effect on August 30, 2007, and remains in effect until September 1, 2012.

## Steps Taken To Avert Shortage… *(Cont.)*

interstate shipment (which includes importation) of unapproved new drugs. Thus, the importation of drugs, whether for personal use or otherwise, that lack FDA approval, violates the Act. Unapproved new animal drugs are any drugs, including foreign-marketed versions of U.S.-approved drugs, which have not been manufactured in accordance with, and pursuant to, an FDA approval.

Unapproved drugs are considered unsafe, and therefore adulterated, under the Act. Under the Act, FDA may refuse admission to any drug that "appears" to be adulterated. The burden is on the importer to prove that the drug sought to be imported is in fact approved by FDA. Absent evidence that the specific drugs sought to be imported from a foreign country have been manufactured pursuant to an approved new drug application in the manufacturing facility permitted under the application, such drugs would appear to be adulterated and could be refused admission to the United States.

CVM is committed to working with sponsors to ensure that an adequate supply of injectable iron dextran product is available. More information is available on CVM's Web site: *http://www.fda.gov/cvm/Irondexupdate.htm*

## Correction

The numbers for the Complaint Coordinators published in *FDA Veterinarian*, 2007, No. IV, for Georgia, North Carolina, and South Carolina are incorrect. The correct number for all three States is 404-253-1169. To be sure you have the most up-to-date listing of phone numbers, please check the Food and Drug Administration's Complaint Coordinator Web site at *http://www.fda.gov/opacom/backgrounders/complain.html*.

# AAFCO Ingredient Definitions: Setting the Standards

*by Jon F. Scheid, Editor*

The Association of American Feed Control Officials (AAFCO) first started defining feed ingredients in 1909, just as the commercial feed industry was beginning to take shape in the United States. Since then, the nature of feed ingredients has become increasingly complex, but AAFCO has continued its role of defining ingredients, and now the Association has an agreement to formally work with scientists from the Food and Drug Administration to ensure the safety of ingredients.

AAFCO's function is to ensure the development and implementation of laws, regulations, standards, definitions, and enforcement policies for regulating animal feed throughout the United States. AAFCO itself has no enforcement authority, but its members do. AAFCO's membership includes regulatory officials from each State who have the authority for ensuring the safety of feed. Although members of the feed industry and the public may participate with AAFCO and its committees, only regulatory agencies and officials are actually members and able to vote and conduct other official business.

FDA recently recognized AAFCO's process for developing its ingredient list by signing a Memorandum of Understanding (MOU) with AAFCO. (See related story, "CVM, AAFCO Sign Agreement on Feed Ingredient Listing," on page 3.) The MOU specifies how FDA can work with the Association in reviewing the ingredient petitions submitted for new ingredient listings or for modifications of existing listings.

Acceptable feed ingredients along with their definitions are listed in *AAFCO's Official Publication (OP)*, published annually. New ingredients are added or existing definitions changed by means of petitions submitted by industry representatives. The petitions are reviewed by an AAFCO investigator, who has the responsibility for the applicable category of ingredients. AAFCO has more than 30 feed ingredient investigators, each with a different ingredient specialty.

Most of the investigators belong to State feed control agencies, but six, including Shannon Jordre, who is chair of AAFCO's Ingredient Definitions Committee and a Consumer Safety Officer with FDA's Center for Veterinary Medicine, work for FDA. (Mr. Jordre's ingredient specialty is miscellaneous and special purpose feed ingredient products.)

When a petition arrives, an AAFCO investigator or FDA scientist reviews it to make sure it contains the information required by The Guide to New and Modified Ingredient Definitions in the *OP*, such as

*(Continued, next page)*

# FDA's Food Protection Plan Recently Unveiled; Safety Enhancements for All Imports Also Announced

*by Walt D. Osborne, M.S., J.D., Assistant Editor*

After 6 months of intensive work to develop a food safety strategy, the Food and Drug Administration released its comprehensive Food Protection Plan on November 6, 2007.

The concerted effort began in May 2007 with the appointment of Dr. David Acheson as Assistant Commissioner for Food Protection. In announcing the plan, Commissioner of Food and Drugs, Dr. Andrew C. von Eschenbach, called it a "forward-oriented concept that uses science and modern information technology to identify potential hazards ahead of time as a means to keeping the American food supply safe." The plan identifies internal administrative actions designed to achieve a more proactive and strategic food safety and defense system, and it also recommends legislative changes to strengthen FDA's ability to continue protecting Americans and their pets from foodborne illness.

A safe food supply includes both human and animal food and feed. To that end, Dr. Stephen Sundlof, Director of FDA's Center for Veterinary Medicine, has been a key player in the development of the Agency's new initiative. The Food Protection Plan is the end-product of months of study, analysis of consumer demographics and buying trends, an awareness of the vast growth of foreign imports, close consultation with many Federal agencies, and an in-depth review of the Agency's existing food safety mechanisms.

The year 2007 was marked by nationwide recalls of contaminated peanut butter that resulted in 300 illnesses and 50 hospitalizations. Contaminated spinach was implicated in more than 200 illnesses, 3 deaths, and more than 100 hospitalizations. And reports of kidney failure and deaths in cats and

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# AAFCO Ingredient Definitions *(Continued)*

information about the ingredient and its intended use (including limitations). The investigator also makes sure the petition includes copies of the scientific literature cited concerning the product's safety, and presents any concerns about toxicity or carcinogenicity, Mr. Jordre said.

Mr. Jordre said that investigators submit nearly all petitions to FDA for a safety review. FDA may not need to review petitions requesting only simple changes, such as a change to an ingredient's nomenclature, he added.

Any time an ingredient presents a safety concern to the animal that consumes it, or the use of the ingredient will create a food safety risk, FDA will recommend against AAFCO adopting a definition until the ingredient has been the subject of an approved food additive petition.

If FDA finds that a proposed new ingredient is suitable for use in animal feeds, the AAFCO investigator will then submit the request to AAFCO's Ingredient Definitions Committee during one of the two public meetings AAFCO holds each year. If accepted by AAFCO, the definition will appear in the next edition of the *OP*. In the meantime, the sponsor may market a product after receiving a letter from FDA saying that the Agency will use regulatory discretion and not take action against the use of the ingredient, when labeled and used as directed.

The ingredient listings in the *OP* reflect the increasing complexity of the feed industry over time. Some of the earliest definitions, dating back more than 80 years, were relatively straight forward. For example, "Ground Ear Corn" and "Wheat Bran" were added to AAFCO's official list prior to 1920. More recent additions, such as "Soybean Meal, Dehulled, Mechanical Extracted," added in 2004, show how new technology used in ingredient manufacturing has changed the type of ingredient submitted for a definition and listing in the *OP*.

Copies of the *OP* are available from AAFCO through its Web site, at *http://www.aafco.org/*.

# FDA's Food Protection Plan *(Continued)*

dogs led to a recall of nearly 200 brands of pet food.

Over the past few years, FDA has worked diligently to address microbial and other food safety hazards associated with both domestic and imported food products. As Dr. Sundlof has pointed out, the Agency's continuing challenge has been the dramatic increase in the volume of imported human and animal food. Specifically, the volume of FDA-regulated products has doubled in the past 5 years, and 60 percent of these product shipments are food products, valued at $49 billion; roughly 15 percent of our food supply now comes from outside the United States.

### *Three elements of protection*

The plan addresses both food safety and food defense for domestic and imported products, and it is integrated with the Administration's Import Safety Action Plan that was announced the same day. That plan is discussed in further detail below. The Food Protection Plan consists of a three-pronged approach: prevention, intervention, and response. All three of these have both internal aspects that the Agency can carry out on its own, as well as legislative authority aspects that would necessitate statutory changes by Congress.

Internally, FDA's plan will involve preventing foodborne contamination by promoting increased corporate responsibility for the prevention of foodborne illnesses at the onset. This aspect of the plan also includes identifying food vulnerabilities and assessing risks, as well as expanding the understanding and use of effective mitigation measures.

The plan will also need intervention at critical points in the food supply chain, with a focus on inspections and product sampling based on risk, as well as enhanced risk-based surveillance. FDA also plans to improve the detection of food system signals that indicate contamination.

Lastly, the Agency acknowledges that in order to minimize harm to humans and animals from a foodborne illness, a rapid response is crucial. Even though FDA has made improvements in this area, the Agency realizes more can be done to further improve its immediate response mechanisms. Going hand-in-hand with this element of the plan is the need for improved risk communication to the public, industry, and other stakeholders.

### *Cross-cutting principles*

FDA envisions four important cross-cutting principles that will allow a comprehensive food protection approach along the entire production chain:

(1) Focus on risks from production to contamination over a product's life cycle. This focus includes consideration of the areas that might fall victim to both intentional and unintentional contamination, such as the point at which the food is grown or produced, and the points of processing, distribution, and storage as well. It also includes handling and storage of the food once it is in consumers' homes.

(2) Target resources to achieve maximum risk reduction. Many variables define a risk, and all of these must be considered, including whether consumption of a food will result in illness from contamination, how that contamination occurred, and the severity of the illness if it does occur.

(3) Address both unintentional and deliberate contamination. FDA has

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# FDA's Food Protection Plan *(Continued)*

devoted significant efforts over the past 6 years to address defense of the food supply against deliberate attack—something that food safety efforts have not traditionally included.

(4) Use science and modern technology systems. To fully support the implementation of the plan, FDA plans to enhance its information technology capabilities and further integrate its information systems. FDA's plan emphasizes the need to know the underlying science that is pivotal to understanding how and where a particular food becomes contaminated and what risks are associated. From there, the priority becomes the need to minimize the likelihood of any harm.

### *Possible enhanced authority*

Legislative changes in the three basic areas of FDA's Food Protection Plan would involve partnering with Congress to seek FDA authority to do such things as: prevent intentional adulteration by terrorists or criminals; accredit highly qualified third parties for voluntary food inspections; require electronic import certificates for food shipments of designated high-risk products; have enhanced access to food records during emergencies; and issue a mandatory recall of food products when voluntary recalls are not effective. This latter enforcement tool has been explored and discussed in the past. Although FDA currently has the statutory authority to seize adulterated or misbranded food, this tool is not always practical when contaminated products have already been widely distributed. Most recalls of FDA-regulated products are handled voluntarily by product manufacturers or distributors. However, there are occasional situations where a firm is unwilling to carry out a recall. In these situations, it would be extremely useful for FDA to require a product recall in order to ensure a quick and complete removal of an adulterated and potentially dangerous product from the distribution channels.

### *Import Safety Action Plan*

As mentioned above, FDA's Food Protection Plan is integrated with the Administration's Import Safety Action Plan, which was released the same day by the Interagency Working Group. President Bush created the Working Group on Import Safety in July 2007. The Group was charged with carrying out an extensive review of the U.S. import system and identifying opportunities for enhancing import safety. The Action Plan represents the culmination of thoughtful dialogue among 12 Federal departments and agencies, months of hands-on information-gathering, and feedback from the public.

The Import Safety Action Plan is a comprehensive approach that provides 14 specific short- and long-term recommendations and 50 action steps to better protect consumers and enhance the safety of the increasing volume of imports entering the United States. It follows the same three organizing principles as the Food Protection Plan: prevention, intervention, and response. It is described as a strategy that moves from a "snapshot" at the U.S. border to a "video" of the product life cycle that focuses on prevention with verification. At its core is the need to ensure that safety is built into all products before they reach our Nation's borders. The Action Plan is broad in scope and applies to consumer products, foods and feeds, and medical products, including medications.

***The Import Safety Action Plan is a comprehensive approach that provides 14 specific short- and long-term recommendations and 50 action steps to better protect consumers and enhance the safety of the increasing volume of imports entering the United States.***

### *In closing*

Simply stated, implementation of FDA's Food Protection Plan and the Administration's Import Safety Action Plan will lead to less illness and fewer injuries to the public and a reduced likelihood of a successful terrorist attack on our food and consumer product supply. Our public health mandate requires nothing less than that.

To download a copy of the full Food Protection Plan, go to: *http://www.fda.gov/oc/initiatives/advance/food/plan.html* or for a pdf version go to *http://www.fda.gov/oc/initiatives/advance/food/plan.pdf*. Copies of the Import Safety Action Plan may be obtained by going to: *http://www.importsafety.gov*

# Comings and Goings

### *New Hires*

*OFFICE OF NEW ANIMAL DRUG EVALUATION*

- Schuyler Winstead, Staff Fellow

*OFFICE OF SURVEILLANCE AND COMPLIANCE*

- Linda Walter-Grimm, Staff Fellow/ Veterinary Medical Officer

### *Departures*

*OFFICE OF MANAGEMENT*

- Linda Callahan, Program Management Officer (retired)

*OFFICE OF NEW ANIMAL DRUG EVALUATION*

- Cuc Schroeder, Mathematical Statistician
- Debra Offenbacher, Biological Aide
- Bernadette Abela-Ridder, Staff Fellow
- Anthony Stone, Office Automation Clerk

# "Rome-ing" with CVM's Representative to Recent FAO Conference

*by Walt D. Osborne, M.S., J.D., Assistant Editor*

I am sure that most readers are familiar with the expression, "When in Rome, do as the Romans do." It is actually a somewhat loose translation of a quote from the fourth century Bishop of Milan, St. Ambrose. But unfortunately, for most government officials who attend conferences on important topics in foreign lands, there is little time or opportunity to absorb the local culture. This was borne out firsthand by Dr. Daniel McChesney, Director of CVM's Office of Surveillance and Compliance, who attended the "Joint Food and Agriculture Organization of the United Nations (FAO)/World Health Organization (WHO) Expert Meeting on Animal Feed Impact on Food Safety" at FAO's headquarters in Rome, Italy, October 8-12, 1007.

I recently had an opportunity to spend a few moments with Dr. McChesney to learn more about the conference and to see what it is like to attend such meetings.

"It's just another day at the office, only you get on a plane," Dr. McChesney commented. The grandeur that was (and is) Rome was only a fanciful notion for Dr. McChesney, who barely had a chance to see the top of St. Peter's Basilica and a few other sights in the distance from the eighth floor balcony of the FAO headquarters building.

The purpose of the conference was to review the current knowledge on animal feed and its impact on food safety to assist efforts by the Codex Alimentarius Commission (part of FAO) to develop further risk management guidance on the issue at the international level. As set forth in the "Charge" letter from FAO/WHO, a concomitant objective of the meeting was to formulate advice on the issue to share with Member Countries and international organizations. This year's conference brought together representatives from the World Organisation for Animal Health (OIE), the European Commission (EC), and 13 other countries: Australia, Brazil, Canada, China, Denmark, Germany, India, Israel, Italy, Netherlands, Russia, and the United States. Only four representatives in attendance were not associated with a government or the EC.

The assembled representatives met as a large group to discuss related topics that covered three general areas: the European Union (EU) and United States views of feed safety as it relates to food safety; toxicology (i.e., microbials, chemicals, and mycotoxins) and its role in feed and food safety; and contaminants (naturally occurring ones, those legally introduced into feed ingredients during their manufacture, and those possibly added as deliberate acts of terrorism). In addition, risk management as it pertains to additives in animal feed was discussed.

### *Report of the proceedings*

Sometime in January 2008, a report on the proceedings from the FAO/WHO Conference will be made available in English, Spanish, and French on the FAO/WHO Web site. Preparation of this report is a fairly detailed and complex process, involving several iterations of the draft document before release of the final product.

Dr. McChesney noted that the Rome conference was conducted entirely in English, although some conferences are offered with simultaneous translations in Spanish and French, which can sometimes be problematic for Asian attendees.

Other somewhat thorny issues involve the various countries' different nuances of meanings for certain terms. For example, certain products that the United States regards as drugs, such as those used to treat coccidiosis, are considered food additives by the EU. This difference can pose significant challenges during the discussions and when the report is being prepared. When issues like this arise, the default position is usually the Codex definition of a drug.

In Rome, one of the participants served as a reporter for each presentation and summarized the discussion. Once all the presentations were summarized, the compiled document was reviewed and vetted line by line by the entire group of conference representatives. Once agreed upon, a final draft was prepared by the Secretariat of the conference, and the entire group had one last opportunity to ensure that all concepts agreed upon were accurately captured. The Secretariat will then send this next iteration of the document electronically to all the participants, who are given one week to review and comment. At this point, FAO will incorporate any minor edits, and the document is then translated into Spanish and French and published on the Web site. It is also made available in hard copy.

### *All roads lead to Rome?*

This famous catchphrase, attributed to Julius Caesar, has stayed in our common parlance for more than 2,000 years. For those attending an FAO conference, their taxi will take them to Viale delle Terme di Caracalla, where the flags of many nations flutter in the Roman air to greet anyone entering FAO headquarters. But as Dr. McChesney learned on his first trip to the Eternal City, the other roads of Rome remained untraveled for him and his colleagues but sparked his interest enough so that he hopes to return another day when he does not have to present a paper.

When asked about the value of this and similar FAO/WHO conferences, Dr. McChesney answered, "Just being able to hear international animal feed experts share their knowledge on this globally important topic was well worth it. Meanwhile, my wife's vivid description of her view of the Sistine Chapel will have to suffice." Eccellente!

# Codex Committee on Veterinary Drug Residues Acts on Several Documents at 17th Session

*by Brandi Robinson, Executive Secretary to the United States Delegation*

At its meeting earlier this year, a Codex Alimentarius Commission's (CAC) committee on animal drug residues, which is hosted by the United States and chaired by Dr. Stephen Sundlof, the Food and Drug Administration's Director of the Center for Veterinary Medicine, made decisions about several pending documents covering the safety of drug residues in food and formed many *ad hoc* electronic Working Groups (EWGs) to deal with some arising issues.

The committee, titled the "Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF)," held its 17th Session September 3-7, 2007, in Breckenridge, CO. The session was attended by delegates from 46 Member countries, 1 Member organization, and official "Observers" from 7 international organizations. CCRVDF is one of the many General Subject Committees that have been established by the CAC.

The CAC was established jointly by the World Health Organization (WHO) and the Food and Agriculture Organization (FAO) of the United Nations in the early 1960s and was designed to be an international reference point to aid countries in development of standards for food safety and consumer protection to protect consumers and alleviate trade concerns. The CAC's purpose is to compile the "Codex Alimentarius," a collection of standards, guidelines, codes of practice, principles, and other recommendations.[1]

While the CAC compiles and adopts the food standards to be included in the Codex Alimentarius, there are many committees and task forces that develop the new standards and texts for adoption by the CAC, including the CCRVDF.

The CCRVDF has four major goals as described in its terms of reference, which define the purpose of this Committee:

1) to determine priorities for the consideration of residues of veterinary drugs in foods;
2) to recommend maximum levels of such substances;
3) to develop codes of practice as may be required; and
4) to consider methods of sampling and analysis for the determination of veterinary drug residues in foods.[2]

In accordance with the terms of reference established by the CAC, the CCRVDF prioritizes a list of veterinary drugs used in food-animals that should be evaluated or re-evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). The JECFA evaluates veterinary drugs to see if an Acceptable Daily Intake (ADI) and Maximum Residue Limits (MRLs) can be recommended for each. An ADI indicates the maximum amount of a veterinary drug that humans can consume daily without the drug causing health problems.

The MRL is generally calculated from the ADI, but sometimes this calculation takes into account other factors. The MRL is the maximum amount of a residue of a veterinary drug that can be in a specific animal tissue (muscle, fat, liver, etc.), as indicated by the ADI. A single veterinary drug will have only one ADI suggested, but may have different MRLs for different animals and tissues combinations. Although the MRLs may be different, they are calculated to prevent consumers from exceeding the established ADI for the drug.

When experts on the JECFA have completed their evaluation, they recommend an ADI and MRLs to the CCRVDF or, in the event they cannot make those recommendations for a particular drug, they explain the reason no recommendation can be made.

The CCRVDF deliberates over the recommended MRLs from JECFA and, using the Codex Step procedure (see sidebar, "The CAC Step Procedure for Reviewing Documents"), recommends them to the CAC for adoption as Codex Standards and inclusion in the Codex Alimentarius.

The CCRVDF also develops any other guidances as needed. Each of these guidances follows the Codex Step Procedure in order to become a Codex standard. These texts are developed by the CCRVDF, through Physical or Electronic Working Groups. Electronic Working Groups work over the Internet and with e-mail, while Physical Working Groups work through face-to-face meetings. Both types of work groups are made up of Member Countries and Member non-government organization delegations. One example of a text that recently completed the Step procedure and became a Codex Standard is the "Code of Practice to Minimize and Contain Antimicrobial Resistance" (CAC/RCP 61-2005).

*(Continued, next page)*

[1] WHO and FAO. (2006). Understanding the Codex Alimentarius (3rd ed.). Rome, Italy.

[2] WHO and FAO. (2006). Codex Alimentarius Commission Procedural Manual (16th ed.). Rome, Italy.

# Codex Committee . . . *(Continued)*

### *CCRVDF decisions from 17th Session*

**Flumequine:** At its 16th session, held May 2006 in Cancun, Mexico, the CCRVDF requested information on registered uses of flumequine with the understanding that if such information was not received, work on the MRLs for flumequine in shrimp would be discontinued. As the CCRVDF did not receive information regarding the registered use of flumequine, the committee members agreed to discontinue work on these MRLs.

**MGA:** The CCRVDF could not reach consensus on the advancement of the MRLs for melengestrol acetate (MGA). The CCRVDF agreed to retain the draft MRLs for MGA in cattle tissue at Step 7 with the understanding that the European Community (EC) will provide new data for a reevaluation of MGA by JECFA. If no new information is forthcoming, or if JECFA reaffirms its decision, the CCRVDF agreed that it would advance the MRLs for MGA to Step 8 at its 18th Session.

**Colistin:** The CCRVDF agreed to advance the draft MRLs for colistin in cattle, sheep, goat, pig, chicken, turkey, and rabbit tissues, in cattle and sheep milk, and in chicken eggs to Step 8.

**Ractopamine:** The CCRVDF agreed to advance the draft MRLs for ractopamine in cattle and pig tissues to Step 8, while acknowledging the strong reservation of the delegations of the EC, Switzerland, and Norway. While many delegations supported the advancement of MRLs for ractopamine to Step 8, the members of the delegation of the EC stated that they could not support that advancement, in view of the fact that their legislation did not allow the use of beta-agonists for growth promotion. (Ractopamine is a beta-agonist.) The CCRVDF noted that the EC delegation's justification for not supporting the advancement of the MRLs to Step 8 was not based on any articulated public heath concern.

**Erythromycin:** The CCRVDF agreed to advance the proposed draft MRLs for erythromycin in chicken and turkey tissues to Step 5/8.

**Triclabendazole:** The CCRVDF agreed to place triclabendazole on the "Priority List for Reevaluation" by JECFA and, in doing so, to return the proposed draft MRLs for triclabendazole in cattle, sheep, and goat tissues to Step 2. The CCRVDF agreed to consider at its next meeting, its 18th Session, the MRLs recommended by the JECFA.

### *Other actions*

The CCRVDF agreed to use the comments submitted by the delegations of the United States and the EC as a starting point for an in-session working group to revise the draft "Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food Producing Animals" for consideration by the plenary. The in-session working group was successful in revising the draft guidelines. After consideration of the revised draft guidelines, the CCRVDF agreed to circulate the document at Step 6 with a view to further consider the document at its 18th Session and forward it to the Commission for final adoption. The CCRVDF agreed that this process will provide countries with an opportunity to consider the revision in detail, analyze the specific provisions, and evaluate the implications for their implementation.

The CCRVDF agreed to establish an *ad hoc* EWG to prepare a discussion paper to address the future of the Compendium of Methods that had been maintained by the Physical Working Group on Methods of Analysis for Residues of Veterinary Drugs in Foods, the link between analytical methods of advancing the Codex MRLs to Step 8, and the criteria necessary for analytical methods to be assessed and considered acceptable. The members of the CCRVDF agreed that they would not re-establish the Physical Working Group before its 18th Session.

The CCRVDF agreed to forward the "Priority List of Veterinary Drugs for Evaluation or Reevaluation"

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## U.S. Delegation to CCRVDF

The U.S. Delegation to the Codex Committee on Residues of Veterinary Drugs in Food (CCRVDF) is composed of individuals from various Federal agencies, private industry, and organizations. The Delegation holds several meetings and communicates through e-mail to prepare for each CCRVDF session. The draft U.S. positions are presented at a public meeting prior to each session and are open for public comment.

The United States is the host country for the CCRVDF and Dr. Stephen F. Sundlof, Director of the Center for Veterinary Medicine (CVM), is the chairman. The U.S. Delegate is Dr. Steven D. Vaughn, Director of the Office of New Animal Drug Evaluation, CVM.

If you are interested in participating in the U.S. Delegation activities, contact the U. S. Codex Office (uscodex@fsis.usda.gov).

# Codex Committee . . . *(Continued)*

by JECFA to the 31st Session of the Commission. This list included: dexamethasone (proposed by Canada), tylosin (proposed by Germany and the International Federation for Animal Health [IFAH]), avilamycin (proposed by Brazil and IFAH), malachite green (proposed by Germany), tilmicosin (proposed by United States), monensin (proposed by United States and IFAH), narasin (proposed by United States and IFAH), triclabendazole (proposed by Australia), and melengestrol acetate (proposed by the EC).

Malachite green was included on the "Priority List" requesting JECFA to consider a literature review and advise the CCRVDF whether this substance can be supported for use in food-producing animals, as the available data were probably not sufficient to derive an ADI and MRLs.

The CCRVDF also agreed to establish an *ad hoc* EWG to prepare a Priority List of Veterinary Drugs for Evaluation or Reevaluation by JECFA and a working document listing veterinary drugs of potential interest, based on Annex 1 to the "Report of the Physical Working Group on Residues of Veterinary Drugs without ADI/MRL" (document CX/RVDF 07/17/12).

The CCRVDF considered the six recommendations that were provided by the report of the Working Group on Residues of Veterinary Drugs without ADI/MRL (CX/RVDF 07/17/12). The Committee agreed to postpone discussion on "Recommendation A: Complete List of Evaluations/Decisions Made Publicly Available" until its next session. On "Recommendation B: Specific Veterinary Drugs," the CCRVDF agreed to establish an *ad hoc* EWG to develop risk management recommendations for veterinary drugs with no ADI and/or

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## Codex Alimentarius Step Procedure for Reviewing Documents

The Codex Alimentarius Commission (CAC) and all of the associated committees utilize an eight-step procedure in developing and adopting standards for the Codex Alimentarius. The text for each standard must go through this procedure before adoption as a Codex standard.

Before any project is undertaken, a project proposal is created and discussed at the committee level. The CAC has created several standing committees and *ad hoc* task forces, each with a defined area of responsibility. If the committee agrees on the proposal for new work, the step procedure starts for that project.

- At Step 1, the proposal for new work is forwarded to the Executive Committee where it is evaluated to ensure that the proposal is within the terms of reference of the respective committee or task force and within the priorities established by the CAC. The Executive Committee acts on behalf of the Commission between sessions of the CAC.
- At Step 2, with the concurrence of the Executive Committee, a draft text is developed at the committee level.
- At Step 3, the draft text is then circulated to all member countries and interested parties for comment.
- At Step 4, the draft text and comments are reviewed at the committee level or task force and a new draft is developed if necessary.
- At Step 5, the new draft text, once it is prepared, is forwarded to the CAC for review and endorsement by any relevant General Subject Committee, because the work of the Committee applies to all commodity standards.
- At Step 6, if the CAC agrees that the draft text should proceed, the approved draft is re-circulated to the member countries and interested parties for another round of comments.
- At Step 7, comments on the approved draft are addressed at the level of the specific committee or task force. The committee or task force then submits the draft to the CAC for adoption at Step 8.
- At Step 8, member countries and interested parties have another opportunity to comment on the text before it is formally adopted by the CAC.

Once a text is adopted, the Codex Secretariat publishes it as a Codex standard. While every standard goes through this process, the timeframe required to complete these steps varies. The respective committee or task force may be able to complete several steps between Sessions. There is also an accelerated process. After Step 4, the respective Committee or task force may choose to advance the text to Step 5/8 instead of Step 5. At Step 5/8, the text is forwarded to the CAC, where it is reviewed and formally adopted as a Codex standard.

# Codex Committee . . . *(Continued)*

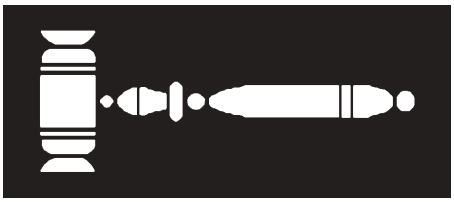
MRLs due to specific health concerns, pending formal approval by the Commission. The CCRVDF noted that the delegations of Australia, New Zealand, and the United States opposed the proposal for new work as proposed by the EC, due to a lack of clarity of the objectives, parameters, and the likely form of this final product and how it could be used.

The CCRVDF agreed with and endorsed "Recommendation C: Scientific Evaluation," "Recommendation D: Prioritisation," "Recommendation E: Closing Data Gaps," and "Recommendation F: Evaluation of Consignments" with some amendments and noted that the JECFA secretariat stated that the expert group from Recommendation C would not be possible with JECFA's current resource constraints.

The CCRVDF agreed to establish an *ad hoc* EWG on "Risk Management Options and Topics" to prepare a discussion paper that would make appropriate risk management recommendations on various issues to the CCRVDF for further consideration and action. The EWG would also collate new proposals with relevant background information and appropriate recommendations to the CCRVDF.

The 18th Session is tentatively scheduled to be held in 2009. The location has not yet been determined.

# Regulatory Activities



### *Warning Letters*

The Food and Drug Administration issued a WARNING LETTER to Jim Wilson, John Wilson, partners, and to Wesley S. Killion, Feedlot Manager of Beef Northwest Feeders LLC of Boardman, OR, for violations of the adulteration provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA). Specifically, the firm sold a steer for slaughter as food that was found to have residues of the drug sulfadimethoxine at 2.13 parts per million (ppm) in the liver tissue and 1.20 ppm in the muscle tissue. A second steer that was sold by the firm was found to have residues of the same drug at 1.36 ppm in the liver tissue and 1.17 ppm in the muscle tissue. A tolerance of 0.1 ppm has been established by FDA for residues of sulfadimethoxine in the uncooked edible tissues (21 Code of Federal Regulations [CFR] 556.640(b)). Having exceeded the established tolerance, both animals were adulterated under section 402(a) of the FFDCA. The firm was also found to have administered Albon® S.R. (sulfadimethoxine) sustained release bolus without following the pre-slaughter withdrawal time set forth in the approved labeling, and it did so without the supervision of a licensed veterinarian, in violation of 21 CFR 530.11(a). Furthermore, the extralabel use resulted in an illegal drug residue. Because the extralabel use of this drug was not in compliance with 21 CFR 530, the drug was also unsafe under section 512(a) of the FFDCA.

Christopher J. Elbe, owner of the Chris and Tracey Elbe Dairy Farm of West Bend, WI, received a WARNING LETTER from FDA for offering an animal for sale that was adulterated under section 402(a) of the FFDCA. Specifically, the firm shipped a dairy cow for slaughter as food that was found to have residues of penicillin at 0.49 ppm in the kidney tissue. A tolerance of 0.05 ppm has been established for residues of penicillin in the uncooked edible tissues of cattle as codified in 21 CFR 556.510. The presence of this drug in kidney tissue from this animal in this amount caused the food to be adulterated within the meaning of section 402(a) of the FFDCA. The firm also failed to maintain animal treatment records and it lacked an adequate inventory system for determining the quantities of drugs used to medicate its livestock.

Similar violations of the adulteration provisions of the FFDCA were cited in a WARNING LETTER from FDA to Edward J. Eury, Jr., of Knoxville, MD, who sold a veal calf for slaughter as food. Tissue samples of the animal revealed the presence of 4.39 ppm of sulfamethazine in the muscle tissue and 5.98 ppm in the liver tissue. A second veal calf that was also sold for food was shown to have 15.80 ppm of the same drug in the muscle tissue and 22.01 ppm in the liver tissue. In addition, this animal was found to have residues of the drug neomycin in the kidney tissue at 69.27 ppm. These drug levels all exceeded the tolerances established by FDA in 21 CFR Part 556 and rendered the animals adulterated under section 402(a) of the FFDCA.

FDA issued a WARNING LETTER to James M. Lopez, President and Chief Executive Officer of Tembec, Inc., of Quebec, Canada, for violations of the adulteration and misbranding provisions of the FFDCA. The firm's feed binding agents, RW25 (marketed under the label names A. Mas and Dresbond AC), RW26 (also marketed under the label names Aqua-Tech II and Aquabond CM), and UP60 (marketed under the label name Dresbond AC), were adulterated within the meaning of section 402(a) of the Act. In addition, the firm's product, RW26, was misbranded within the meaning of section 403(i). Specifically, an FDA inspection found that the firm manufactured products using several unapproved food additives. First, it added melamine to RW26, and second, it added urea formaldehyde condensation polymer to RW25, RW26, and UP60. Third, the firm added hexamethylenetetramine to certain batches of RW26. Under the FFDCA, any substance intentionally added to a food must be used in accordance with a food additive regulation, unless it is Generally Recognized As Safe (GRAS) or meets one of the enumerated exceptions. Melamine, urea formaldehyde condensation polymer, and hexamethylenetetramine are not approved food additives, and FDA is not

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# Regulatory Activities *(Continued)*

aware of any basis to conclude that they are GRAS for use in animal feed. The presence of these unsafe food additives in the products caused them to be adulterated under section 402(a)(2)(C)(i) of the Act. In addition, the ingredient lists on the labels for the RW26 bulk product, Aqua-Tech II, and Aquabond CM (products using RW26) did not disclose the presence of melamine. The failure to disclose this information on the label of the products caused them to be misbranded under section 403(i)(2) of the Act because they were fabricated from two or more ingredients and their labels failed to declare the common or usual name of each ingredient.

Duane K. Oxendale, owner of Duane Oxendale finishing operation, received a WARNING LETTER from FDA for violation of the adulteration provision in section 402(a) of the FFDCA. Specifically, Mr. Oxendale sold a heifer that was slaughtered for human food that was found to contain 40.96 ppm sulfamethazine in the liver and 23.91 ppm of the drug in the muscle. A tolerance of 0.1 ppm has been established by FDA for residues of sulfamethazine in the uncooked edible tissues of cattle (21 CFR 556.670). These higher levels rendered the animal adulterated. Mr. Oxendale was also warned of providing a false guaranty, a prohibited act under section 301(h) of the FFDCA. He was also cited for failure to maintain treatment records.

FDA issued a WARNING LETTER to Matthew Toms, owner of Matthew Toms dairy operation, Walkersville, MD, for violations of the adulteration provisions of sections 402(a) and 501(a) and of the safety provision in section 512(a) of the FFDCA. Specifically, Mr. Toms consigned a culled adult dairy cow for slaughter as food through a hauler. Tissue samples taken by USDA inspectors revealed the presence of the drug penicillin at 0.17 ppm in the kidney tissue. A tolerance of 0.05 ppm has been established for this drug in the uncooked edible tissues of cattle (21 CFR 556. 510). The higher level rendered the meat adulterated under section 402(a). In addition, Mr. Toms was cited for failure to use penicillin in conformance with its approved labeling in violation of section 501(a) of the FFDCA. The drug was also used extralabel in violation of section 512(a) of the FFDCA, because such use was not done under the supervision of a licensed veterinarian.

Bryan Vander Dussen, Partner in Golden View LP, Ontario, CA, received a WARNING LETTER from FDA for violations of the adulteration provisions in sections 402(a) and 501(a) of the FFDCA. Specifically, Mr. Dussen sold a dairy cow for slaughter as human food that was found to contain residues of the drug, Banamine (flunixin meglumine) in the liver tissue at 0.852 ppm. A tolerance of 0.125 ppm has been established for residues of this drug in the liver of cattle (21 CFR 556.286), and therefore, the animal was adulterated under section 402(a). In addition, Mr. Dussen was cited in the WARNING LETTER for failure to use Banamine in conformance with its approved labeling in violation of section 501(a) of the FFDCA. The drug was also used extralabel in violation of section 512(a) of the FFDCA, because such use was not done under the supervision of a licensed veterinarian. Adequate treatment records were also found to be lacking.

Violations of section 501(a) and 512(a) of the FFDCA are the bases for the issuance of a WARNING LETTER to Ben J. Weaver of Clymer, NY. An inspection of his veal calf- raising operation revealed that the new animal drug, Duo Pen (Penicillin G Benzathine and Penicillin G Procaine Injectable Suspension), was adulterated because it was not used in conformance with the extralabel use parameters set forth in section 501(a), 512(a), and 21 CFR Part 530. The drug was administered contrary to both the approved labeling instructions and those of Mr. Weaver's veterinarian. In addition, Mr. Weaver adulterated the animal feed that was fed to his veal calves within the meaning of section 501(a) of the FFDCA by adding NeoMed 325 Soluble Powder (Neomycin Sulfate) and Uniprim Power for Horses (Trimethoprim and Sulfadiazine) to Strauss Veal Feed Market Blend milk replacer. The extralabel use of drugs in or on animal feed is specifically prohibited by section 512(a) of the Act and by 21 CFR Part 530.

FDA has issued a WARNING LETTER to Michael Brent Masterson of the Tri Mast Dairy, Lebanon, KY, for violations of the adulteration provisions in sections 402(a) and 501(a) of the FFDCA. Specifically, this dairy consigned a dairy cow for slaughter as food without notifying either the hauler or the auction officials of the medication status of the animal; tissue samples revealed the presence of the drug sulfadimethoxine at 1.36 ppm in the muscle tissue and at 1.82 ppm in the liver tissue. A tolerance of 0.1 ppm of this drug has been established by FDA for residues in the edible tissues of cattle (21 CFR 556.640). FDA's investigation also revealed that the Tri Mast Dairy administered sulfadimethoxine bolus to treat mastitis in a dairy cow, which is not an approved use of this drug. This extralabel use was not done by or on the lawful order of a licensed veterinarian within the context of a valid veterinarian/client/patient relationship, and, therefore, was a violation of section 512(a) of the FFDCA and of 21 CFR Part 530.

Mrs. Maria Borges, owner of the J&M Dairy, Artesia, NM, has received a WARNING LETTER from FDA for violations of the adulteration provisions of the FFDCA (sections 402(a) and 5102(a)). An analysis of tissues taken from a dairy cow sold for slaughter as food revealed the presence of the drug penicillin at 0.47 ppm in the kidney tissue and at 0.15 ppm in the liver tissue. A tolerance of 0.05 ppm has been established by FDA for residues of this drug in the edible tissues of cattle (21 CFR 556.510). Tissue samples taken of a second dairy cow sold for slaughter as food revealed the presence of the drug sulfadimethoxine at 0.43 ppm in the muscle tissue and at 0.76 ppm in the liver tissue. FDA has set a tolerance of this drug of 0.1 ppm in the edible tissues of cattle. Therefore, the excess amounts of these two drugs rendered both animals adulterated pursuant to section 402(a) of the FFDCA. In addition, the dairy was cited for violation of the adulteration provisions in section 501(a) of the FFDCA, because both drugs mentioned above were not used in conformance with their approved labeling.

A WARNING LETTER was issued by FDA to Ray and Eric Veldhuis, owner and general manager, respectively, of the Veldhuis North Dairy, Ballico, CA, for violation of section 402(a) of the FFDCA. Tissue samples taken from a dairy cow that was offered for slaughter as food revealed the presence of the drug sulfadimethoxine at 0.35 ppm in the liver and at 0.13 ppm in the muscle tissue. The tolerance for this drug in the edible tissues of cattle has been set by FDA at 0.1 ppm (21 CFR

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# Regulatory Activities *(Continued)*

556.640). The firm was also cited for lacking an adequate system to ensure that animals medicated have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Food from animals held under such conditions is adulterated within the meaning of section 402(a).

Anthony Richard Van Ryn, partner in the Moreno Valley Dairy, Moreno Valley, CA, was cited in a WARNING LETTER for violating section 402(a) of the FFDCA. Specifically, the firm offered for slaughter as food a dairy cow that was found to have residues of the drug sulfadimethoxine in the liver at 5.36 ppm and in the muscle tissue at 4.38 ppm. A second dairy cow was found to have residues of the same drug in the liver at 6.67 ppm and in the muscle tissue at 8.15 ppm. All of these levels exceeded the tolerance of 0.1 ppm in the edible tissues of cattle set by FDA in 21 CFR 556.640, thus rendering the animals adulterated. FDA's investigation also found that the firm held animals under conditions that were so inadequate that medicated animals bearing potentially harmful drug residues were likely to enter the food supply.

### *Recalls*

A firm-initiated Class I recall is ongoing by United Pet Group, Inc., of Cincinnati, OH, for 143,163 packs of Dingo Brand "Chick'n Jerky" for dogs, cats, and ferrets. The affected products were manufactured by Shanghai Peidi Brand Intl. Co. Ltd., Shanghai, China. The products are being recalled because they have the potential to be contaminated with *Salmonella*. Distribution was nationwide.

ChemNutra, Inc., of Las Vegas, NV, is carrying out a firm-initiated Class I recall of 972 metric tons of Chinese wheat gluten in 25 kg paper bags. The product, manufactured by a firm in mainland China, was found to contain melamine. Distribution of the product was nationwide.

A Class I firm-initiated recall is ongoing by Del Monte Food, Pittsburgh, PA, for 137,457 cases of jerky sticks and snacks for dogs. The reason for the recall was that wheat gluten used to manufacture the products tested positive for melamine.

Cereal By Products of Mount Prospect, IL, is carrying out a firm-initiated Class I recall of 405,482 lbs. of rice protein powder that was made in China. The rice protein powder, which was distributed in Missouri and Kansas, was found to be contaminated with melamine.

A Class I firm-initiated recall is ongoing by Hills Pet Nutrition, Inc., Topeka, KS, for 11,681 units of Prescription Diet Feline. The product was found to be made with raw material wheat gluten that was contaminated with melamine. The product was distributed nationwide and internationally.

Nestle Purina Petcare Co., St. Louis, MO, is conducting a Class I firm-initiated recall of 418,071 cases of ALPO prime cuts pet foods that were distributed nationwide and in Indonesia. The products were made with wheat gluten that was contaminated with melamine.

A total of 63,049 cases of Ol' Roy and Happy Tails dog food products are involved in an ongoing firm-initiated Class I recall by Del Monte Foods, Pittsburgh, PA. Wheat gluten used to manufacture these products tested positive for melamine. The products were distributed nationwide.

Sunshine Mills, Inc., Red Bay, AL, is carrying out a firm-initiated Class I recall of 24,398 cases of pet biscuits and treats that were found to contain wheat gluten that was contaminated with melamine. The products were distributed nationwide.

A Class I firm-initiated recall is ongoing by Menu Foods Midwest Corp., Emporia, KS, for approximately 127,700 cases of various cat food products that were distributed nationwide and in Canada. Prompted by reports from FDA of the presence of melamine in cans of cuts and gravy pet food produced in Menu Foods' Canadian facility, the firm identified a single interplant transfer of the ChemNutra-supplied wheat gluten, shipped from its plant in Emporia, KS, to its plant in Streetsville, Ontario. This wheat gluten was subsequently used in the production of pet food in December 2006 and January 2007.

Menu Foods Midwest Corp., Emporia, KS, is also conducting a firm-initiated Class I recall of 53. 3 million cans or pouches (2,384,722 cases) of "cuts and gravy style" pet foods that had been implicated in illness and deaths of cats. These products were distributed nationwide, and in Canada and Mexico.

American Nutrition, Inc., of Ogden, UT, is conducting a firm-initiated Class I recall of 15,594,120 cans and 111,660 bags of various dog, cat, puppy, and kitten food that was distributed nationwide. The reason for the recall is that the products may be contaminated with melamine, which was contained in the imported rice protein concentrate ingredient.

A total of 155 metric tons of rice protein concentrate is the subject of an ongoing, firm-initiated Class I recall by Wilbur Ellis Company, San Francisco, CA. The product, which was manufactured by Binzhou Futian Biology Technology Co. Ltd., Shandong, China (Mainland), was found by FDA to be contaminated with melamine. Distribution of the product occurred in Utah, Kansas, New York, and Missouri.

J Foods, Inc., of Bern, KS, is conducting a firm-initiated Class I recall of 26,668 lbs. of "Spa Select Chicken and Brown Recipe for Kittens" that was distributed nationwide. The product was made with an ingredient pre-blend which was made using a rice protein concentrate that has been found by the supplier and FDA to contain melamine, an unapproved food ingredient.

A Class I, firm-initiated recall is ongoing by Natural Balance Pet Food, Inc., of Pacoima, CA, involving 305,863 bags of the Venison & Brown Rice Dog Food and 174,378 bags of the Venison & Green Pea Cat Food under the "Dick Van Patten's" label. The firm's sample analysis has shown products, which were distributed nationwide and in Canada, contain melamine.

Lortscher Agri Service, Inc., of Bern, KS, has completed a Class I recall of one batch of its preblend made with rice protein concentrate for pet food that contained melamine. Distribution of the recalled product was limited to Kansas.

The Scoular Co. of Minneapolis, MN, is conducting a Class I recall of seven lots of a batch of wheat gluten (308, 644 lbs.) made by Xuzhou Anying Biologic Technology Development Co., LTD., of Peixian, China (Mainland). The reason for the recall is that FDA detected the presence of melamine in certain lots of the wheat gluten. Distribution of the product was limited to Alabama and Nebraska.

Mars Pet Care Co. of Everson, PA, has completed a firm-initiated Class I recall of 1,623 bags of dog food that were distributed in New York, Massachusetts, New

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# Regulatory Activities *(Continued)*

Jersey, Connecticut, and Pennsylvania. The recall was undertaken because of a possible contamination with *Salmonella*.

A Class I firm-initiated recall is ongoing by Castleberry's Food Company, August, GA, for 114,779 cases of dog food under the Dick Van Patten's Natural Balance label. The products, which were distributed nationwide, and in Canada, Japan, and South Korea, were possibly contaminated with *Clostridium botulinum*.

A total of 18,000 lbs. of frozen chicken and turkey dog and cat food products are involved in an ongoing firm-initiated Class I recall by BRAVO!! LLC, Vernon, CT. The products are being recalled because of contamination with *Salmonella* and/or *Listeria monocytogenes*.

Nutra Blend LLC, Neosho, MO, has completed a Class II recall of 86,700 lbs. of its 50-lb. premix products, including Diamond Pet SG PMX #1, Diamond Pet SG PMX #2, Diamond Holistic Premix, and Kirkland Holistic Premix. The products were recalled because some of the raw material dehydrated parsley powder used in the manufacture of the premixes was found to contain *Salmonella*. Distribution was limited to Missouri, South Carolina, and California.

A Class III recall has been completed by Kent Feeds, Inc., of Muscatine, IA, for 4,315 50-lb. bags and 39.46 bulk tons of the following items: (1) Bulk Kent HP Calf Creep LTD 30R Medicated, containing 30 g/ton Monensin (as Monensin Sodium; (2) Kent First Rate Show Goat 20R Medicated, packaged in 50-lb. bags, containing 20 g/ton Monensin; and (3) Kent 16% Goat 20R Medicated, packaged in 50-lb. bags, containing 20 g/ton Monensin. The recall was conducted because labeling on the products lacks expiration dates. Distribution of the products was limited to Missouri and Kansas.

A Class III firm-initiated recall is ongoing by Virbac AH, Inc., of Fort Worth, TX, for 22,752 units ResiPROX Leave-on Conditioner, 8oz.; active ingredient: Pramoxine HCl 1.5%. The product, a topical conditioner for dogs and cats, is contaminated with bacteria. Distribution of the product was nationwide.

A firm-initiated Class III recall is ongoing by Valley Proteins, Inc., of Winchester, PA, Inc., for more than 13 million pounds of 58% Protein Poultry Meal Blend that were suspected of containing melamine. Distribution was limited to Pennsylvania and Delaware.

Menu Foods Midwest Corp. of Emporia, KS, has recalled 194 separate lines of cuts and gravy style and other products potentially cross-contaminated with wheat gluten. A total of 464, 565 cases of food distributed nationwide, in Canada and Mexico were involved in the Class III recall.

A Class III firm-initiated recall is ongoing by Brown's F M Sons, Inc., of Sinking Spring, PA, for 207 bags of its Squirrel Corn Nuggets in 5 lb. bags. The reason for the recall is that the binding agent that was used (AquaBond) was recalled due to melamine contamination. Distribution was limited to Pennsylvania and Virginia.

Ginger Inc. of Toledo, OH, is carrying out a Class III recall of 1,250 units of various fish feeds under the Ginger, Discovery, and Earl May brand names due to melamine in the products. Distribution was nationwide.

A Class III firm-initiated recall has been completed by SouthFresh Feeds of Demopolis, AL, for 233.9 tons of shrimp feed distributed in Alabama and in the country of Belize. The reason for the recall was that the products were manufactured using an aquatic binder that contained melamine, which is unapproved for use in animal and fish feeds.

A Class III firm-initiated recall is ongoing by Uniscope, Inc., of Johnstown, CO, for 4.9 million pounds of a binding agent that was manufactured after January 2004, was used in animal and fish feeds, and contained melamine. The affected products were distributed both nationwide and internationally.

HBH Enterprises of Springville, UT, is carrying out a Class III recall of 165,740 lbs. of its shrimp pellets that were made from a melamine-containing aquaculture product that were used in a variety of ornamental fish foods. Distribution of the affected products took place nationwide and internationally.

A Class III firm-initiated recall has been completed by ADM Nutrition Alliance, Inc., of Quincy, IL, for 90.65 tons of bulk and 478 50-lb. bags of medicated cattle feed. The reason for the recall was that the binder used in the manufacture of the premixes contained melamine. Distribution of the products took place in South Dakota, Iowa, and Minnesota. The same firm has completed a Class III recall of 18 tons of regular and medicated cattle feed in bulk for the same reason (melamine). Distribution of these products occurred in Nebraska and South Dakota.

Rangen, Inc., of Buhl, ID is carrying out a Class III recall of 10.8 million pounds of various fish feeds that were distributed nationwide. The reason for the recall is that the firm received binder (Aqua Tec II) that was contaminated with melamine from another manufacturer that subsequently used the binder in the manufacture of its finished products. The same company is conducting a Class III recall of Rangen, Inc., fish feed products that were manufactured using an ingredient contaminated with melamine and its analogs. Distribution of the 10.7 million pounds of feed took place in Arkansas, California, Mississippi, Kentucky, Texas, Colorado, Alabama, Virginia, Arizona, Oklahoma, Minnesota, Louisiana, Missouri, and Florida.

More than 1.08 million pounds of shrimp and prawn feed products are involved in a firm-initiated Class III recall by Zeigler Brothers, Inc., of Gardner, PA. The feed ingredient (AquaBond) that was used as a binder in the products, which were distributed nationwide and internationally, contained melamine.

A Class III firm-initiated recall is ongoing by Skretting Company of Canada, Inc., Vancouver, British Columbia, for 727,439 kilograms of non-medicated and medicated fish feeds that were contaminated with melamine. Distribution of the products occurred nationwide.

Royal Canin USA, Inc., St. Charles, MO, is carrying out a firm-initiated Class III recall of approximately 322, 600 bags of various dog and cat foods that were distributed nationwide. The pet foods contain rice protein concentrate of Chinese origin found to be contaminated with cyanuric acid, an unapproved food additive. The same firm is recalling 48,486 bags of pet foods under the KASCO label for the same reason, along with approximately 262,000 bags of various sizes of dog and cat foods under the Royal Canin and Sensible Choice labels that were also distributed nationwide.

*(Continued, next page)*

## Regulatory Activities *(Continued)*

Tembec BTLSR, Inc., Toledo, OH, is carrying out a firm-initiated Class III recall of 5,196,060 lbs. of pet foods under the A. MAS and Dresbond labels because the products contain melamine, an unapproved food additive. The products were distributed in Mexico and Ecuador.

Contamination with melamine has also led to a firm-initiated Class III recall by LCP Products, Long Beach, CA, for 75 bags of its Lamb Stock Mix in 50-lb. bags. Distribution of this product was limited to Utah.

Rangen, Inc., of Buhl, ID, has completed a firm-initiated Class III recall of 10.8 million pounds of aquaculture and fish feeds that were distributed nationwide. The firm had received a binder product, Aqua Tec 110, that was contaminated with melamine from another manufacturer and subsequently used in the manufacture of their finished products.

# Approvals for September and October 2007

## CVM has published in the *Federal Register* notice of the approval of these New Animal Drug Applications (NADAs)

- ETOGESIC (etodolac) Injectable (NADA 141-274), filed by Fort Dodge Animal Health, Fort Dodge, IA. The approved NADA provides for the veterinary prescription use of ETOGESIC (etodolac) Injectable in dogs for the control of pain and inflammation associated with osteoarthritis. Notice of approval was published September 7, 2007.

- COMFORTIS (spinosad) (NADA 141-277), filed by Elanco & Co., Indianapolis, IN. The approved NADA provides for the veterinary prescription use of COMFORTIS (spinosad) Chewable Tablets to kill fleas and for the prevention and treatment of flea infestations (*Ctenocephalides Felis*) on dogs for one month. Notice of approval was published October 25, 2007.

## CVM has published in the *Federal Register* notice of the approval of these Supplemental New Animal Drug Applications (NADAs)

- DEXDOMITOR (dexmedetomidine hydrochloride) (NADA 141-267), filed by Orion Corporation, Espoo, Finland. The supplemental NADA provides for the veterinary prescription use of dexmedetomidine hydrochloride injectable solution as a sedative and analgesic to facilitate clinical examinations and procedures, and minor dental procedures in cats. Notice of approval was published September 7, 2007.

- DRAXXIN (tulathromycin) Injectable Solution) (NADA 141-244), filed by Pfizer, Inc., New York, NY. The supplemental NADA provides for the addition of a pathogen—*Mycoplasma bovis*—to the indication for use of tulathromycin solution in cattle, by subcutaneous injection, for the control of respiratory disease in cattle at high risk of developing bovine respiratory disease. Notice of approval was published September 26, 2007.

- ADEQUAN i.m. (polysulfated glycosaminoglycan) (NADA 140-901), filed by Luitpold Pharmaceuticals, Inc., Animal Health Division, Shirley, NY. The supplemental NADA provides for the use of ADEQUAN i.m. (polysulfated glycosaminoglycan), an injectable solution, in horses and dogs by veterinary prescription for noninfectious degenerative and/or traumatic joint disease. The supplemental NADA provides for a revised food safety warning for use in horses. Notice of approval was published October 5, 2007.

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# Approvals for September and October 2007 *(Continued)*

## *Supplemental New Animal Drug Applications (Continued)*

OPTAFLEXX (ractopamine hydrochloride), MGA (melengesterol acetate), RUMENSIN (monensin), and TYLAN (tylosin phosphate) (NADA 141-233), filed by Elanco Animal Health, a division of Eli Lilly & Co., Indianapolis, IN. The supplemental NADA provides for the use of these Type A medicated articles to make dry and liquid four-way combination Type C medicated feeds used for increased rate of weight gain, improved feed efficiency, and increased carcass leanness; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*; for suppression of estrus (heat); and for reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium* (*Actinomyces*) *pyogenes* in heifers fed in confinement for slaughter during the last 28 to 42 days on feed. The supplemental NADA provides for an increased level of monensin in four-way combination Type C medicated feeds containing ractopamine, melengestrol, monensin, and tylosin for heifers fed in confinement for slaughter, a revision to bacterial pathogen nomenclature, and an increase in the cattle liver tolerance. Notice of approval was published October 5, 2007.

EQUIPHEN (phenylbutazone) Paste (NADA 140-958), filed by Luitpold Pharmaceuticals, Inc., Shirley, NY. The supplemental NADA provides for the use of EQUIPHEN (phenylbutazone) Paste in horses for relief of inflammatory conditions associated with the musculoskeletal system. The supplemental NADA also provides for a revised human food safety warning on product labeling. Notice of approval was published October 25, 2007.

## CVM has published in the *Federal Register* notice of the approval of this Conditional Approval (CA)

AQUAFLOR-CA1 (florfenicol) (CA 141-259), filed by Schering-Plough Animal Health Corp., Summit, NJ. The conditional approval provides for the use of AQUAFLOR-CA1 (florfenicol), a Type A medicated article, by veterinary feed directive to formulate Type C medicated feed for the control of mortality in catfish due to columnaris disease associated with *Flavobacterium columnare*. The drug is conditionally approved as of April 13, 2007; the effect of the final rule was delayed until October 9, 2007, pending establishment of 21 CFR Part 516.

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

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