

CHAPTER: Post-Approval Monitoring of Animal Drugs, Feeds and Devices

SUBJECT: Illegal Residues In Meat, Poultry, Seafood, and Other Animal Derived Foods		IMPLEMENTATION DATE 08/01/2005
		COMPLETION DATE Continuous
DATA REPORTING		
PRODUCT CODES	PRODUCT/ASSIGNMENT CODES	
Industry codes: 16, 17, 67-69	71006, 71S006 71004 71003A	

FIELD REPORTING REQUIREMENTS

1. Hardcopy Reporting

For all Federal and State investigations/inspections submit, Field Accomplishments Compliance Tracking System (Facts) Coversheet with endorsement, completed Tissue Residue Evaluation Form(s) (Attachment C), Drug Inventory Survey Form (Attachment G), to the Compliance Information Management Team, HFV-235, Attention: Fran Pell.

2. FACTS Reporting

- a. Report time for all Federal drug residue follow-ups against Program Assignment Code (PAC) 71006. For state inspections of residue violations conducted under contract report time against PAC 71S006. For state inspections of residue violations conducted under cooperative agreements report the time under PAC 71006 with a state position class to identify the work as state-performed. For all inspections include the FSIS sample number in the description field of FACTS.
- b. Report time for follow-up at medicated feed mills against PAC 71004.
- c. Report time for Contamination Response System (CRS) investigations of non-drug residues against PAC 71003A.

PART I – BACKGROUND..... 5

PART II – IMPLEMENTATION..... 8

A. INTRODUCTION 8

B. OBJECTIVES..... 8

C. PROGRAM MANAGEMENT INSTRUCTIONS 8

 1. Inspectional 8

 a. On-Site Inspections by FDA of Meat and Poultry Violations..... 10

 b. On-Site Inspections by FDA of Seafood..... 11

 c. Investigation of Food Animal Marketing Firms 11

 d. Inspections at Aquaculture Farms:..... 11

 e. Inspection of other Animal-Derived Products 12

 f. Extra-label Use..... 12

 g. FSIS Special Programs 13

 h. FSIS Condemnation Practices 13

 2. District Monitor Responsibilities 14

 3. Analytical 15

 4. Program Interaction 16

 5. Inter-Agency Agreements 16

 6. Federal/State Relations 17

PART III - INSPECTIONAL..... 18

A. Inspectional Operations 18

 1. Jurisdiction..... 18

 2. Violation..... 18

 a. Meat and Poultry Residues 18

 b. Seafood and Aquaculture Residues 20

 3. Responsibility 21

 a. Dealer Involvement 21

 b. Veterinarian Involvement..... 22

B. GMP Inspections..... 23

C. Sampling..... 23

 1. Sample Submission 24

 2. Collection Report (CR)..... 24

D. Reporting..... 24

E. Criminal Activity Investigations..... 25

PART IV - ANALYTICAL 26

A. Responsibilities 26

 1. Sample Preparation 26

 2. Tissue Sample Storage 26

PART V - REGULATORY/ADMINISTRATIVE..... 27

A. GENERAL 27

B. INITIAL VIOLATION..... 28

C. REPEAT/MULTIPLE VIOLATIONS 28

 1. Warning Letter 29

 2. Injunction 29

 3. Prosecution..... 30

PART VI - CONTACTS, ATTACHMENTS, AND REFERENCES 32

A. PROGRAM CONTACTS 32

 1. CVM 32

 a. Program Inquiries 32

 b. Technical Guidance 32

 c. Regulatory Inquiries 32

 d. Policy Questions 32

 2. ORA..... 33

 a. Inspectional Inquiries..... 33

 b. Analytical Inquiries..... 33

 c. Federal/State Relations Inquiries..... 33

B. LIST OF ATTACHMENTS..... 33

C. APPLICABLE REFERENCES OR AIDS..... 34

 1. INVESTIGATIONS OPERATIONS MANUAL (IOM): Chapters 4 & 5 Sampling and Inspection. 34

 2. 21 CFR Parts 500-599, Animal Drugs, Feeds, and Related Products. 34

 3. Compliance Policy Guides:..... 34

 4. Compliance Programs 34

 5. Regulatory Procedures Manual. 34

 6. AOAC Official Methods of Analysis, 16th Edition..... 34

PART VII - CVM RESPONSIBILITIES 35

A. Program Evaluation 35

B. Inter-Center Action 35

C. Compliance Information Management Team 35

D. Enforcement and Regulatory Policy Team 36

ATTACHMENT A - USDA REPORTING CODES..... 37

FSIS/USDA Laboratory Reporting Codes 37

USDA TISSUE LOOK-UP TABLE..... 46

MARCIS SPECIES CODES ON USDA RECORDS..... 49

SPECIES/ANIMAL LOOK-UP TABLE USED BY USDA 50

ATTACHMENT B-1 - SAMPLE PRODUCER WARNING LETTER 51

ATTACHMENT B-2 - SAMPLE WARNING LETTER EXTRA-LABEL DRUG USE by VETERINARIAN 54

ATTACHMENT B-3 - SAMPLE WARNING LETTER ILLEGAL DRUG SALE 57

ATTACHMENT B-4 - SAMPLE WARNING LETTER BUYER/DEALER 59

ATTACHMENT C - TISSUE RESIDUE EVALUATION FORM 61

ATTACHMENT D - USDA CONTACTS 74

FSIS Technical Service Center (TSC) 74

FSIS District Offices..... 74

Office of Program Planning, Evaluation, and Enforcement..... 77

Regional Offices..... 77

APHIS Veterinary Services Offices 78

GIPSA..... 82

ATTACHMENT E – GIPSA / TITLE 18 MEMO 83

ATTACHMENT F-1 Example of Slaughter House Affidavit to Document Chain of Custody..... 85

ATTACHMENT F-2 Example of Slaughter Plant Inspector Affidavit..... 86
ATTACHMENT G DRUG INVENTORY..... 87
 AMDUCA Prohibited Drugs List..... 121
ATTACHMENT H - District Monitor Checklist..... 122

PART I – BACKGROUND

This Compliance Program was developed to provide a cohesive framework for the Field to use that would include inspectional priorities, helpful technical information, and resources to facilitate the investigation of residue violations routinely reported to the Food and Drug Administration (FDA) by the United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS). To protect consumers from potentially harmful residues in the food that they eat it is important that inspections are conducted to determine the cause of the illegal drug residues and to develop data descriptive of on-farm practices of management and animal drug use for program decision support, identification of educational needs, and policy development. This program also provides guidance for enforcement measures. The Federal Food, Drug, and Cosmetic Act (the Act)(21 U.S.C. 321(f)) defines food as “(1) articles used for food or drink for man or other animals...and (3) articles used for components of any such article.” (Section 201(f)). Food-producing animals and fish, even though not in their final, edible form, have been held to be food under the statute United States v. Tomahara Enterprises Ltd., Food Drug Cosm. L. Rep. (CCH) 38,217 (N.D.N.Y. 1983) (live calves intended as veal are food) and United States v. Tunte Livestock, 888 F. Supp. 1416, 1423-26 (S.D. Ohio 1995) (live hogs are food). More generally, courts have long held that unprocessed or unfinished articles are or can be food. See Otis McAllister & Co. v. United States, 194 F.2d 386, 387 (5th Cir. 1952) and cases cited there (unroasted coffee beans are food). Thus, live animals raised for food are “food” under the Act.

Tissue residue investigations may reveal:

- the illegal sale of veterinary prescription drugs
- the illegal use of bulk drugs
- the extra-label use of drugs (which includes inadequate pre-slaughter withdrawal period)
- cross-contamination of animal feeds due to poor Good Manufacturing Practices (GMPs) (21 CFR Parts 225 or 226)
- failure to follow good animal husbandry practices
- the misuse of drugs in medicated animal feeds
- the marketing of treated/medicated animals intended for rendering purposes being diverted to slaughter for human consumption
- inadequate animal identification

Protection of the public by assuring a safe meat and poultry supply is a responsibility shared by the USDA Food Safety and Inspection Service (FSIS), the Grain Inspection, Packers and Stockyards Administration (GIPSA), the Animal and Plant Health Inspection Service (APHIS), the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA), The FSIS exercises supervision over the slaughter and processing of meat and poultry products in federally inspected

establishments and is responsible for the safety of these food products. FSIS reports violative residues of drugs, and both violative and non-violative residues of pesticides, and other contaminants in meat and poultry to FDA for follow-up.

The GIPSA works closely with FSIS in regulating animal marketing practices. GIPSA is an enforcement agency within USDA charged with enforcing the Packers and Stockyards Act of 1921 (7 U.S.C. §181) through economic regulation. GIPSA has also assisted FDA in securing producer identification when sales are through auction barns or dealers.

A final rule on swine identification became effective on November 14, 1988. All swine in interstate commerce must be identified and records concerning identification must be maintained. USDA (APHIS and FSIS) is responsible for enforcement. (53 FR 40378, October 14, 1988).

The EPA establishes the tolerances for pesticide residues in meat and poultry. FDA enforces these tolerances.

FDA is responsible for the approval of new animal drugs, including the establishment of tolerances for residues of those drugs in edible tissues. FDA conducts investigations of FSIS-reported residues to determine the party responsible for causing the tissue residue violation and the party responsible for introducing the adulterated food into interstate commerce. The results of FDA investigations have shown that, in most instances, the animal producer is primarily responsible for the illegal drug residues because of failure to comply with drug withdrawal times, other label warnings, use of contaminated animal feeds, use of drugs for unapproved purposes, and employing poor animal husbandry practices. Investigations may also lead to other individuals such as a hauler, buyer, dealer, auction barn, veterinarian, or slaughter house.

FDA has the responsibility to ensure the safety of the seafood supply. In 1995, FDA published the final HACCP (Hazard Analysis and Critical Control Points) regulations for seafood processors (53 FR 40378, December 18, 1995) (21 CFR Parts 123 and 124). The final rule became effective on December 18, 1997. Primary processors of aquaculture products are responsible for ensuring that their HACCP Plans address systems for drug residue control. The Center for Food Safety and Applied Nutrition (CFSAN) issued a Compliance Program Guidance Manual (7304.018), Chemotherapeutics in Seafood, in FY 2002 outlining procedures for sampling aquaculture products to be tested for drug residues. This compliance program addresses sampling of product from both domestic and imported sources.

In 1994, Congress passed legislation that would allow veterinarians to prescribe drugs in a manner inconsistent with the approved new animal or new human drug labeling. This act is called the Animal Medicinal Drug Use Clarification Act (AMDUCA)(21 U.S.C. §360b(a)) and the regulations that implement AMDUCA are published in Title 21 Code of Federal Regulations Part 530. These regulations describe the specific conditions under which extralabel use is permitted.

Expansion of the Tissue Residue program has paralleled the Agency's growing concern about consumer exposure to drug residues in the edible products of food animals. For example, in 2002, the Agency became aware of the use of drugs in the production of honey, to treat diseases of honey bees. This Compliance Program has been expanded to address this concern.

In an effort continually to improve the program, CVM develops new training courses for Federal and State investigators to address identified training needs. CVM also organizes national cooperative meetings with officials from FDA, FSIS, GIPSA, APHIS and individual states, writes educational articles, and conducts industry outreach programs in an effort to provide message-specific information to educate firms on sound drug use and residue prevention practices.

CVM encourages the District Offices to develop cooperative agreements (i.e., contracts, partnership agreements, memoranda of understanding, and informal arrangements) with their state agencies to conduct initial inspections. These inspections are predominantly educational in nature and are extremely important in the prevention of future residues.

For residues detected in seafood products the ultimate goal is to determine the cause of the residue and pursue regulatory action. The current CFSAN sampling program focuses on drugs that are not approved for use in aquaculture.

There are currently only two drugs approved for use in honey bees, oxytetracycline and fumagillin. If a residue is reported of a drug other than the two approved drugs, then the residue was caused by an extra-label use, and may be considered a violation of AMDUCA .

PART II – IMPLEMENTATION

A. INTRODUCTION

This program provides a framework from which each District can fashion its own drug residue control initiatives. CVM requests that Districts receiving reports of violative tissue residues from USDA/FSIS take steps to protect the consumer by either conducting Federal or assigning State onsite investigations at the farm level and other points of responsibility throughout the marketing chain, and to initiate actions commensurate with the findings.

CVM will issue FACTS assignments to request Federal investigation of repeat violators. CVM will also issue inspectional assignments via FACTS for violative residues detected in seafood and other animal derived human food. The Districts are encouraged to recommend enforcement action for such violations.

B. OBJECTIVES

- To conduct investigations/inspections to determine the cause of illegal drug residues and/or shipment of adulterated food.
- To develop data descriptive of on-farm practices of management and animal drug use for program decision support, identification of educational needs, and policy development.
- To obtain correction through voluntary and/or enforcement actions.

C. PROGRAM MANAGEMENT INSTRUCTIONS

1. Inspectional

FDA Districts conduct on-site inspections in the follow-up of violative tissue residue findings of public health concern reported to them by FSIS. In association with these assignments the Districts should investigate all those in the marketing chain who may have acted irresponsibly.

Districts are encouraged to watch for trends or patterns in types of residues or involved parties; for example, the same buyer/dealer involved in a number of residues or a sudden increase in residue reports involving the same drug. The Residue Violation Information System (RVIS) is an excellent source for this type of data on residues.

The Agency's approach to focusing on individual firms for case development will be to use a coordinated team approach when determining which case(s) to pursue. If the District believes that it should develop a case on a specific producer or someone in the marketing chain please contact the Compliance Information Management

Team, HFV-235, Randy Arbaugh or Deborah Cera to discuss investigational approach/priority.

Districts should request intensified sampling of egregious firms in an effort to obtain timely residues to facilitate case development. Please submit such requests via email to the Compliance Information Management Team, HFV-235, Deborah Cera, who will handle coordination with the FSIS Technical Services Center. In order to facilitate successful sample collection please be sure to provide as much relevant information as possible regarding the firm's marketing practices, e.g., what slaughter plant(s) they use, are animals delivered directly to slaughter, or through a middleman (provide name), and on what day of the week do the animals generally go to slaughter.

NOTE:

The current CFSAN Compliance Program, 7304.018, Chemotherapeutics in Seafood, is a sample collection program designed to test for drugs that are not approved for use in aquaculture. If a domestic sample is found to be positive, CVM will issue an assignment for follow-up to document the violation. Case development should be considered for such residues with all questions directed to the Compliance Information Management Team, HFV-235, Fran Pell.

To discuss case development for drug residues in meat and poultry contact the Enforcement and Regulatory Policy Team, HFV-232, Reginald Walker. For all other residues detected in animal derived foods, contact Compliance Information Management Team, HFV-235, Fran Pell, to discuss case development.

Pesticide and industrial chemical residues, mycotoxin contamination, microbiological residues, and heavy metals reported to the Districts by FSIS under its Contamination Response System (CRS) will be covered under the Feed Contaminants Program (7371.003). Under unique conditions, certain violative drug residues may be reported through the CRS. Follow-up investigational time for CRS drug residues should be charged to this program (7371.006). Contact the Enforcement and Regulatory Policy Team, HFV-232, Sandra Washington before initiating a follow-up to a CRS report.

a. On-Site Inspections by FDA of Meat and Poultry Violations

- 1) **Repeat Violators:** This is the **top priority** for FDA inspections/investigations. Firms or individuals who repeatedly present adulterated animals for slaughter may represent a significant public health risk. Therefore, CVM will issue an assignment to the District in FACTS requesting an FDA on-site investigation for each repeat violator. A repeat violator is an individual who sells a slaughter animal whose carcass is found to contain a violative concentration of a drug, pesticide, or environmental contaminant within a 12-month period after the first violation and after receiving the FSIS Notification Letter.
- 2) **First-time Violators:** As resource allow, conduct an on-site inspection/investigation for first-time violators when FSIS reports violative tissue residues for the following situations:
 - Drugs prohibited from extra-label use in food-animal use - chloramphenicol, diethylstilbestrol (DES), nitrofurans (furazolidone, nitrofurazone), or nitroimidazoles (e.g., dimetridazole, ipronidazole), clenbuterol, sulfonamides in lactating dairy cattle (except approved use of sulfadimethoxine, sulfabromomethazine and sulfaethoxyipyridazine), fluoroquinolones, glycopeptides, and phenylbutazone in female dairy cattle 20 months of age or older.
 - Drugs not approved for food animal use: beta agonists (e.g., fenoterol, salbutamol), tranquilizers, etc.
 - Very high level residues, indicating intentional misuse of the drug and/or a complete disregard for the withdrawal period.
 - Drug tissue residues reported under the CRS. These assignments will be issued from CVM.

NOTE:

If none of the above criteria is met on an initial residue violation then resource constraints do not allow for an FDA investigation. Cooperating State agencies should be assigned inspections of all other first-time violators to determine the cause of the residue and to attempt to prevent a repeat violation through education and/or any regulatory action deemed appropriate by the State.

b. On-Site Inspections by FDA of Seafood.

The drugs that are being tested for in Seafood are for unapproved drugs. All violations require an FDA follow-up and a FACTS assignments will be issued by CVM.

c. Investigation of Food Animal Marketing Firms

Focusing on firms/people responsible for the delivery for introduction or the introduction into interstate commerce of adulterated products is an important concept under this program. Experience has shown that investigations can lead to producers, haulers, dealers, auction barns, and buyers, any one of which may be held responsible for the violation. Parties throughout the chain of distribution may act irresponsibly by not determining if animals they handle are medicated or not forwarding this information to the next person or firm in the marketing chain. For example, a dealer or auction barn can take precautions by determining if animals are medicated and selling them as such. Dealers have been found to purchase medicated animals supposedly for dog food and then offer them for sale at a slaughterhouse for human food. Please relay these incidences to the local Grain Inspection Packers and Stockyards Administration. Any animal offered for sale at a USDA licensed slaughter facility is for human food. Implementation of the marketing chain strategy should be coordinated at the local and national levels between FDA, FSIS, APHIS, and GIPSA and State agencies. For example, we can request that FSIS increase sampling of a producer or dealer's animals. The goal is to use the expertise and the legal tools possessed by each group. FDA is the lead agency in collecting evidence and initiating regulatory action.

Districts should work closely with the Enforcement and Regulatory Policy Team, HFV-232, Reginald Walker at the onset of selecting a firm or individual for possible regulatory action.

d. Inspections at Aquaculture Farms

There are six drugs approved for use in aquaculture. They are: oxytetracycline, sulfadimethoxine/ormetoprim, formalin, chorionic gonadotropin, tricaine methanesulfonate and sulfamerazine. Sulfamerazine is not currently marketed. The brand names, species approved for and conditions of use can be found at:

<http://www.fda.gov/cvm/aqualibtoc.htm#ApprovedDrugs>

All of the drugs in the current CFSAN testing program are not approved for aquaculture use in the United States. The drugs may be labeled for non-food fish and later diverted to food fish producers. It is important to determine if the drug manufacturer or distributor is marketing these drugs for this use. If an FDA approved drug was used in an extra label manner determine if a veterinarian was involved. If so, follow-up with the veterinarian as appropriate. Determine why the producer used the drug and, if not prescribed by a veterinarian, what information was used by the producer to determine how to use the drug.

e. Inspection of other Animal-Derived Products

During inspections of other animal-derived product producers, the drug identified by the residue may have been used in an extra-label manner, so determine if there was a veterinarian involved with the use, and whether all of the conditions of AMDUCA were met.

f. Extra-label Use

The Animal Medicinal Drug Use Clarification Act became law in 1994 and the regulations implementing this law can be found in Title 21 Code of Federal Regulations Part 530 (21CFR 530). The regulations describe the conditions under which FDA approved drugs can be used in a manner inconsistent with the approved labeling as long as such use is by or on the lawful written or oral order of a licensed veterinarian within the context of a Veterinary-Client-Patient Relationship (VCPR). This regulation only applies to FDA approved drugs and the use must be therapeutic in that the animal must be sick or might die if not treated, and there needs to be a valid veterinarian client patient relationship. For more details refer to the 21CFR 530.

While AMDUCA does not permit the extra-label use of an FDA approved drug in or on feed, CVM recognizes that for some species of animals this is not always practical. FDA published a Compliance Policy Guide (CPG Sec. 615.115), 'Extra-Label Use of Medicated Feeds for Minor Species', which permits the extra-label use of medicated feed for minor species under specific circumstances. Briefly, this extra-label use can only be done upon the order of a veterinarian, the feed must be manufactured according to the approval and there is no reformulating of the feed. For aquaculture species there are two approved medicated feeds for food fish. More details can be found at:

http://www.fda.gov/ora/compliance_ref/cpg/cpgvet/cpg615-115.html

g. FSIS Special Programs

(1) FAST

FAST (Fast Antimicrobial Screen Test) is a microbial inhibition screening test. It was designed to be used by an FSIS veterinarian or a designated food inspector in a slaughter plant, for the detection of antibiotic and sulfonamide residues in livestock kidney tissue. The FAST test reacts with at least 56 different antimicrobials.

The FAST test is based on the principle that if animal tissue contains a residue of previously administered antimicrobial, fluid from the tissue will inhibit the growth of a sensitive organism on a bacterial culture plate. The plates are examined for zones of inhibition around the sample, which constitutes a positive test. The significance of the FAST test is its high degree of sensitivity over the old CAST (Calf Antibiotic Sulfa Test) test and the fact that test results can be obtained after a minimum of **6 hours** incubation to a maximum of 24 hours from the time the plate is incubated.

If the result is negative the carcass is released. If the result is positive, tissue samples (muscle, kidney, and liver) are sent to the laboratory for bioassay testing and the carcass is retained pending laboratory results.

(2) STOP

STOP (Swab Test on Premises) is an in-plant test currently being used by FSIS plant inspectors on suspect animals to test for antibiotic microbial inhibitors. STOP-positive carcasses are retained pending the receipt of results of confirmatory tests, which are automatically conducted in FSIS laboratories.

h. FSIS Condemnation Practices

Where FDA has established a tolerance for a marker residue in a target tissue FSIS will condemn the entire carcass when a violative residue is confirmed in the target tissue. For other drugs, if the liver or kidney is found to contain violative residues, they alone are condemned. In all cases if the muscle contains a violative residue then the entire carcass is condemned.

An exception to the above is the routine condemnation of the entire carcass of any non-ruminating veal calf found to contain a hormonal implant.

2. District Monitor Responsibilities

Each District should assign an individual to serve as a monitor for this compliance program. The monitor's duties should include the following:

- Review Weekly Residue Report. CVM, in consultation with the District Program Monitor, will issue assignments to the District in FACTS for FDA Investigations and enter the appropriate assignment activity code in RVIS. The Monitor should enter all activity codes for assignments and follow-ups.
- Once an investigation is completed. The Program Monitor should, review the EIR for newly identified sources, name/address, firm-type corrections, and additional middleman information. This information should then be entered into RVIS.
- The Monitor should promptly enter appropriate activity codes covering Repeat Violator Status, Completed Investigations, Regulatory Reserve Samples, and Regulatory Actions taken. Every violation followed up by an FDA or State investigator should have the FDA Responsibility Flag entered into RVIS as responsible, not responsible, or involved. This information is needed before FSIS can post a firm to its Web Report of Repeat Violators.
- Periodically review RVIS for violator/violation trends, e.g., specific middleman involvement in a number of violations or an increase in the number of residues for a specific drug. Notify the Compliance Information Management Team, Deborah Cera, Fran Pell, or Randy Arbaugh if you believe that an investigation is warranted. Keep abreast of RVIS enhancements.
- Assign State investigations per guidance contained in Part II.C.1.a. of this program. Provide the state with computer-generated Attachment C forms for TRIMS data collection and remind them to complete the Drug Inventory Survey Form (Attachment G).
- Review completed EIRs/Attachment C forms and Drug Inventory Survey forms to determine if required fields have been completed. Discuss any incomplete reports with the appropriate parties to improve the quality of future data reported.
- For all Federal and State investigations/inspections submit a copy of the Field Accomplishments Compliance Tracking System (Facts) Coversheet with endorsement, completed Tissue Residue Evaluation Form(s) (Attachment C), Drug Inventory Survey Form (Attachment G), to the Compliance Information Management Team, HFV-235, Attention: Fran Pell

- Request that the inspectors/investigators contact the District Program Monitor before the start of an on-farm follow-up so that they can get an updated violator history to ensure that additional residues have not occurred since the assignment date.
- Request the Regulatory Reserve Portion of samples for all firms that might become the subject of an enforcement action. Requests should be timely to ease FSIS's burden of sample retention. All samples not requested will be destroyed after 12 months. All requests should be directed to Don Gordon, Donald.Gordon@FSIS.USDA.Gov, Tel. No. 314-263-2680 ext. 341.
- Monitors should maintain a list of samples that they have requested to be stored in an FDA laboratory. Periodically review this list and request a Sample Destruction Notices (SDNs) be prepared through the appropriate channels in your Districts once it becomes clear that the District will not be initiating enforcement action against a firm.
- Provide the District Director, and Directors of Compliance and Investigations, where appropriate, with a list of local Repeat Violators and associated District activities, at least twice annually.
- Serve as a clearinghouse for distribution of information to cooperating State officials.
- Inform District management of all CVM/ORA-sponsored training initiatives. Recommend training of all Federal/State personnel conducting residue investigations.
- Maintain routine communications with local representatives from FSIS, APHIS, GIPSA, and the States.
- Work with CVM to distribute Industry outreach materials appropriate to address local residue concerns.

3. Analytical

Ordinarily FSIS will analyze tissues and conduct confirmatory analyses. FDA confirmatory analyses of tissue samples collected, analyzed, and confirmed by FSIS are not necessary to support regulatory action. Other tissue samples **should not** routinely be sent to the Denver District Laboratory. FSIS has agreed to run confirmatory tests on those samples that the FDA District needs to support casework. For example, if during an investigation of a neomycin residue it is revealed that a sulfa was used in combination with neomycin, a portion of the reserve sample can be sent back to FSIS for analysis for sulfas.

One exception to the above would be when FSIS reports finding a hormone implant in a veal calf submitted by a "Repeat Violator". The District should request that the reserve sample of the actual implant be shipped to the Denver District Laboratory where hormones present in the implant will be identified.

Please contact the Compliance Information Management Team, HFV-235, Deborah Cera, to facilitate requests for additional analyzes.

4. Program Interaction

When the investigation implicates a medicated feed produced by either a commercial feed mill or an on-farm mixer/feeder, conduct a comprehensive GMP inspection. For example, carbadox residues in swine generally result from feed and not dosage form drugs. Charge all time expended for GMP inspections to the Feed Manufacturing Program PAC 71004, regardless of whether done at the feed mill or the mixer-feeder. Remember, the regulations in 21 CFR Part 225 sections 225.10 to 225.115 apply to facilities manufacturing one or more medicated feeds for which an approved medicated feed mill license is required. The regulations in 21 CFR Part 225 sections 225.120 to 225.202 apply to facilities solely manufacturing medicated feeds for which an approved medicated feed mill license is not required.

When the tissue residue results from a non-drug chemical contaminant, such as pesticides, metals, mycotoxins, or microbiological contaminants, charge the time expended for follow-up investigations to PAC 71003A - Feed Contaminants Program.

The success of the Agency's program to support the prevention of the introduction and amplification of BSE in the United States is dependent on the ability of investigators to identify violative firms and operations. While initial efforts by Federal and State investigators have identified and inspected most renderers and commercial feed mills, continued efforts are needed to identify and continue to inspect all firms subject to the regulation. Ruminant feeders are an important obligation that should receive additional attention. Unless another BSE inspection has recently been conducted, add-on BSE inspections should be conducted for each ruminant feeder visited during a tissue residue follow-up. Charge time expended for such inspections to PAC 71009 – BSE/Ruminant Feed Ban Inspections.

Tissue residue monitors should maintain close contact with their Regional Milk Specialists and State milk authorities. RVIS reports of dairy animal violations are supplied to these individuals on a quarterly basis. One long-term goal is for involved agencies to share all available information related to drug residues (milk and meat) in dairy animals. This effort can maximize resource utilization in targeting enforcement actions and promoting effective residue controls.

5. Inter-Agency Agreements

DATE OF ISSUANCE: August 1, 2005
MINOR CORRECTIONS: August 23, 2005
FORM FDA 2438

See MOU 225-85-8400 - MOU between FDA, FSIS, and EPA regarding regulatory activities concerning residues of drugs, pesticides and environmental contaminants in foods, which went into effect on February 1, 1985.

6. Federal/State Relations

States participate in this program under agreements (contract, MOU, partnership, and informal) to conduct inspections. The emphasis of the State programs is to determine the cause of the residue and to provide producer education in an effort to prevent future violations.

Regions/Districts are urged to develop cooperative work sharing agreements with **each of their** states. General guidance for the development of work-sharing agreements is found in RPM Chapter 3-20. Maintain a high level of communication with cooperating States and share with them the periodic RVIS reports of State findings and results of program evaluations.

For information on the formation of agreements with States, contact the Division of Federal-State Relations, HFC-150.

PART III - INSPECTIONAL

A. Inspectional Operations

The three elements of a case for which evidence should be collected by the investigator are: jurisdiction, violation(s), and responsibility. The order in which the evidence is gathered is at the District's discretion. Because of the public health significance, the District should be attentive to steps that can be taken to prevent adulterated animals from going to market. For example, if an on-farm investigation reveals that veal calves, due to go immediately to market, are still being fed a neomycin-containing milk replacer, steps should be taken to prevent their marketing by requesting State assistance (quarantine power or other enforcement tools) and by alerting the FSIS Regional Office of the potential offering of these animals at USDA licensed slaughter facilities.

1. Jurisdiction

Establish and document interstate (IS) commerce.

Obtain affidavits from the involved auction/sales barn or slaughter facility or processing plant attesting to the fact that it routinely deals in interstate commerce and include the approximate percentage of IS business. Examples of recent records of IS sales may also be appropriate as part of the documentation with slaughter facilities or the processing plant, a current affidavit (desirably no older than 6 months for injunction or prosecution cases) is acceptable for establishing IS commerce. Call the Enforcement and Regulatory Policy Team, HFV-232, Reginald Walker for assistance/advice.

Notify the producer or other implicated person that animals or meat from animals he/she offers for sale may move in interstate commerce, even if the animals are not delivered directly into interstate commerce. In those cases in which extra-label use or other drug adulteration or misbranding charges may be appropriate, interstate jurisdiction over the drug(s) should be documented.

2. Violation

a. Meat and Poultry Residues

FSIS reports violative residues to FDA on a single-animal basis for FDA to follow-up. FSIS sample results show the amount and type of the drug detected. FSIS analysis may be limited to the identification of one drug. If investigational evidence supports the presence of another drug, call the Compliance Information Management Team (HFV-235), Deborah Cera or Fran Pell so that she can request analysis of the tissue sample for the additional compound. Animal identity problems should be worked out with the FSIS Technical Services Center, Dr. Julie Cornett, 402-221-7400, or local APHIS

Animal Identification Specialist. ID Specialists can be reached by contacting the local Veterinary Services Office. (See Attachment D) The identification of the responsible party given by FSIS **should** be positively confirmed by the FDA investigation. Use ear tag numbers, lot numbers, or other means to adequately link the animal to the producer/party responsible for the violation. FSIS, APHIS, and GIPSA can assist in responsible party identity.

NOTE: When doing a follow-up of a repeat violator that has received FDA prior warning, an affidavit should be obtained from all FSIS in-plant inspectors associated with each residue. Please notify the FSIS Technical Services Center, Dr. Julie Cornett, 402-221-7400 to arrange for and authorize a time for you to meet with the appropriate inspector(s) to obtain necessary documentation. (See Attachment F for an example of the kind of affidavit needed.)

Medication/treatment resulting in illegal residues may be performed by the grower/feedlot, veterinarian, or in rare cases, by the dealer, hauler, auction barn, buyer, or slaughterhouse. Because of the number of people involved in the marketing chain, it is essential that time factors and animal identity is well-documented. For example, if an animal is slaughtered within 24 hours of leaving the farm, it is unlikely that a middleman treated the animal. Collect affidavits from middlemen affirming that whether or not drugs were used on the animal.

Many residues are caused by conditions conducive to potential tissue residue violations at the farm, i.e., "poor husbandry practices." When doing an investigation at the producer, determine and describe the conditions you observe. That should include at least the following:

- (1) Inventory all drugs on the premises (See Attachment G).
- (2) Determine and list other drug-containing products, such as medicated feeds, or other drug sources, that could have been, or are being used in food-producing animals. Although most violative residues result from direct misuse of drugs in the animals, tissue residue investigations have revealed residues resulting from cross-contamination of withdrawal feeds with medicated feeds in feeding bins, or from feeding calves milk from treated cows. If possible, physical or documentary samples of drugs or feeds should be collected if implicated in the residue.
- (3) Describe where the drugs are stored, how they are stored, and who has access to the drugs.

- (4) Determine who administers medication and try to interview those individuals about their medication practices (who determines what animals are to be medicated, how are the medications selected, how are dosages determined, etc.).
- (5) Determine identification systems and segregation/quarantine practices, if any, for medicated animals.
- (6) Determine if medication records are maintained. Describe the record system. Do they include the date of medication, the drug used, the dosage administered, milk withholding and slaughter withdrawal times, etc.
- (7) Determine how the producer has assured that **withdrawal times** are met prior to marketing.

Look for and document fraudulent buying or selling practices (violations of Packers and Stockyards Act and regulations) and the giving of false certificates or guarantees. GIPSA has been successful in levying substantial administrative fines for such violations. All swine in interstate commerce must be identified and records concerning identification must be maintained (9 CFR Part 71). This rule was published by USDA (**APHIS and FSIS**) and they will be responsible for its enforcement. If FDA Field offices encounter problems with identification of swine, these should be reported to, and worked out with your APHIS Animal ID Coordinator. We are also requesting that you alert CVM to these problems by reporting them to the Compliance Information Management Team, HFV-235, Deborah Cera.

We recommend objectionable conditions be listed on a FDA 483, and discussed with management at the conclusion of the inspection. Record the applicable information on Attachment C.

b. Seafood and Aquaculture Residues

All drugs that the Agency is currently testing for in seafood are not approved for use in aquaculture. The list of approved drugs can be found at:

<http://www.fda.gov/cvm/aqualibtoc.htm#ApprovedDrugs>

Some compounds are not traditional drugs but based on their intended use, 'to treat or mitigate a disease' they can be considered drugs. One example of a compound that falls into this category is malachite green. When doing an investigation at the producer, determine and describe the conditions that you observe. That should include at least the following:

- (1) Inventory all drugs on the premises.

- (2) Determine and list other drug-containing products, such as medicated feeds, or other drug sources, that could have been, or are being used in fish. Although most violative residues result from direct misuse of drugs in the fish, tissue residue investigations have revealed residues resulting from cross-contamination of withdrawal feeds with medicated feeds in feed storage bins. If possible, physical or documentary samples of drugs or feeds should be collected if implicated in the residue.
- (3) Describe where the drugs are stored, how they are stored, and who has access to the drugs.
- (4) Determine who administers medication and try to interview those individuals about their medication practices (who determines what fish are to be medicated, how are the medications selected, how are dosages determined, etc.).
- (5) Determine identification systems and segregation/quarantine practices, if any, for medicated fish. Keep in mind fish are normally medicated in their pond/raceway/net pen. They would medicate all the fish in that group. Brood fish may be individually medicated.
- (6) Determine if medication records are maintained. Describe the record system. Do they include the date of medication, the drug used, the dosage administered, and slaughter withdrawal times, etc.
- (7) Determine how the producer has assured that **withdrawal times** have been met prior to marketing.

3. Responsibility

Determine and document who committed the violation, i.e., who did what, and when. This would include: misuse of approved drugs, use of illegal and unapproved drugs, GMP violations, and poor animal husbandry practices that could contribute to causing the violative drug residue, and the issuance of false certificates, guarantees, or any other statement on the medication status of the animal offered for sale. Keep in mind that more than one firm/individual in the marketing chain may be held responsible for tissue residue violations.

a. Dealer Involvement

Persons involved in handling, transporting, holding, and marketing food-producing animals should be encouraged to establish systems to ensure that if **they administer** drugs to animals in their control or care, those drugs are used properly, and to establish systems to prevent potentially hazardous drug residues in edible animal products.

Persons who do not administer medications but who acquire animals for sale for slaughter (such as livestock dealers) should also establish and implement a recordkeeping system. This system should include information on the source of the animal and whether the animal has been medicated (when, with what drug, and the withdrawal period) to preclude marketing of adulterated edible animal tissues.

Specifically, describe the system the dealer has for the following:

- (1) Their system to identify the animals they purchase or acquire with records to establish traceability to the source of the animal;
- (2) Their system to determine from the source of the animal whether the animal has been medicated and with what drug(s); and,
- (3) If the animal has been medicated, their system to withhold the animal from slaughter for an appropriate period of time to deplete potentially hazardous residues of drugs from edible tissues. If they do not hold the medicated animal, then describe how they assure that the animal is clearly identified and sold as a medicated animal.

Such persons may be subject to regulatory action if they market animals containing illegal residues and have failed to take reasonable precautions to prevent the sale of adulterated food [21 U.S.C. 331(a)].

Seafood does not have dealers like the terrestrial animals. Fish haulers are sometimes either associated with the producer or the processor. Determine if any drugs or chemicals are put into the fish haul truck tanks to reduce stress to fish.

b. Veterinarian Involvement

If the investigation reveals that the drug involved in causing the residue was prescribed, administered, or dispensed by a veterinarian include the following:

- (a) Describe the veterinarian/client/patient relationship that existed at the time the animals in question were treated. Refer to 21 CFR Part 530.
 - Does the veterinarian regularly visit the farm premises and examine the animals?
 - Is the veterinarian aware of the husbandry practices utilized by this firm?

- Did the veterinarian examine, prescribe, or administer the drug to the animal in question?
 - If the veterinarian administered the drug, report the dosage and describe what kind of instructions he/she left for milk withholding and/or pre-slaughter withdrawal times. (Did the producer follow those instructions?)
 - If the veterinarian did not administer the drug, with whom and what kind of instructions did he/she provide for drug administration and milk withholding and/or pre-slaughter withdrawal times? (Did the producer follow those instructions?)
- (b) Describe how the veterinarian established the recommended withdrawal time and how he/she attempted to assure that the producer adhered to that time.
- (c) Describe how the dispensed product was labeled.
- (d) If the drug was one that the veterinarian prepared (by combining 2 or more products, or other manufacturing methods), list the products or ingredients, describe who prepares them, and how they are prepared. Use CPG Sec.608.400 - Compounding of Drugs for Use in Animals and 21 CFR Part 530.13 for additional guidance.

B. GMP Inspections

Conduct GMP inspections at the feed mill or mixer/feeder when either is implicated as causing the residue violation. Use CP 7371.004 for guidance and be sure to use Form 2481 when conducting an inspection. See 21 CFR Part 225 sections 225.120 to 225.202 for GMP requirements for feed mills that do not require a license. The GMP regulations at 21 CFR Part 226 are for the manufacturers of Type A medicated articles.

C. Sampling

Collect samples (including both documentary samples and/or physical samples) to document violative conditions. See IOM Sampling Schedule Chart 16 for both potency and drug carryover in feeds.

If illegal or unapproved drugs, such as chloramphenicol or nitrofurans, are found on a food-producing animal farm, collect documentary samples of seizable-sized lots.

1. Sample Submission

Ship all medicated feed and animal drug samples for drug or microbiological analyses to the Denver Laboratory. Before shipping samples contact the Laboratory Director, Karen Kreuzer, HFR-SW260, at 303-236-3060, to discuss inspectional findings and required sample analyses.

2. Collection Report (CR)

Prepare a CR for the FSIS-collected sample only when regulatory action is being considered. CRs need to be prepared for each drug being used in an extra-label manner and for any other sample collected during the investigation

D. Reporting

Submit, Field Accomplishments Compliance Tracking System (Facts) Coversheet with endorsement, completed Tissue Residue Evaluation Form(s) (Attachment C), Drug Inventory Survey Form (Attachment G) to the Compliance Information Management Team, HFV-235, Attention: Fran Pell. Photocopy necessary forms for District use. The completion of Attachments C and G are essential for the success of the automated database, TRIMS (Tissue Residue Information Management System). Upon request CVM will provide information for comprehensive District reports. TRIMS is extremely useful in identifying trends in causes of tissue residues, e.g., illegal use of bulk drugs, extra-label use of dosage form drugs, medicated feeds, etc.

A copy of the fully completed FACTS coversheet, along with pertinent parts of the memo of investigation or EIR should be forwarded to the FSIS Technical Services Center. Please Fax or email any source information changes to FSIS immediately so they can issue a corrected notification letter to the appropriate individual and update RVIS. It is FDA's responsibility to provide FSIS with updated violator information for RVIS. Do not complete an Attachment C for violations in Seafood or Honey. Send the EIR with attachments to the Compliance Information Management Team, HFV-235, Attention: Fran Pell.

E. Criminal Activity Investigations

When illegal residue investigations uncover activities of a criminal nature, such as using false names, knowingly purchasing medicated animals for slaughter, purchasing animals with the understanding that they will be sold for rendering or other non-human food use and then offering the animals for slaughter for human food, you should consider referring the case to FDA's Office of Criminal Investigations (OCI). This Office has skills, contacts, and expertise that may be invaluable in conducting the investigation and pursuing the appropriate enforcement action. The formal procedure for referral is described in the Investigations Operations Manual (IOM) Chapter 9, Subchapter 980. **If OCI is unable to pursue a specific case, the District should still conduct follow-up inspections in accordance with this program.** OCI may be able to assist in certain areas or FDA investigators may work jointly with OCI agents in the investigation.

PART IV - ANALYTICAL

A. Responsibilities

1. Sample Preparation

Prepare feed samples for drug analysis as described in the AOAC 16th Ed.

2. Tissue Sample Storage

The analyzing FSIS laboratory will retain all FSIS-collected violative samples for up to 12 months. Once the FDA District Office decides that a firm may warrant regulatory action they should immediately request that the pertinent sample(s) be shipped to an FDA laboratory. Please note that unless a sample shipment request is received, all samples will be destroyed by FSIS after 12 months. Samples should be retained by FDA until a compliance action is completed or the firm sufficiently demonstrates its sustained ability to market animals free of violative residues.

Districts should devise a sample accountability system for the FSIS-collected tissue samples. A suggested system would be to prepare a sample accountability card for each sample received using the FSIS laboratory form number as the sample number. By using the form number, a CR would not be prepared, thereby eliminating the problem of how to report time for preparing the CR. A CR would, however, need to be prepared before a case is forwarded for regulatory consideration.

Tissue samples using this system are handled in the same manner as any FDA sample.

An FSIS Directive establishes a formal system to guarantee sample integrity. An intact FSIS official seal should be affixed to the sample container. Contact Compliance Information Management Team, Deborah Cera, if you find this not to be the case routinely. Although FDA would prefer all samples from FSIS to be sealed, the lack of a seal should not deter you from appropriate follow-up.

3. Problem Area Flags (PAF) for PACs

PAC 71003A - PAF (PES, NAR)
 PAC 71004 - PAF (NAR, KIT, DRT, ANT, DRA)
 PAC 71006 - PAF (NAR, DRT, ANT, DRA, KIT)

Note: This only applies to Meat and Poultry samples reported to FDA by USDA, FSIS. Follow C.P. 7304.018, Chemotherapeutics in Seafood, for information on seafood samples for drug residues.

PART V - REGULATORY/ADMINISTRATIVE

A. GENERAL

Enforcement follow-up activity is prioritized by the degree of human health risk potential involved in the residue violation(s). Additionally, enforcement action may be against individual(s) responsible for multiple residue violations involving drugs presenting a lesser human health risk. The following information covers most violative residue situations. Occasionally, however, unique situations are encountered which require new or special investigational or enforcement procedures. Discuss these new or special situations with CVM, Division of Compliance, Enforcement and Regulatory Policy Team, Reginald Walker as they occur so that an acceptable investigational or enforcement strategy can be developed. Also notify and discuss with the Compliance Information Management Team, Deborah Cera proposed joint interagency (FDA//FSIS/GIPSA) enforcement actions against individuals/firms (other than the producer) at the initial stage of development. CVM will contact FSIS, and GIPSA headquarters units and the District will contact FSIS, and GIPSA field units to implement interagency enforcement actions.

For aquaculture questions contact the Compliance Information Management Team, Fran Pell. For other animal derived human foods contact Deborah Cera, or Fran Pell.

Animals are considered food under the Act when offered or intended for slaughter for human food at slaughter facilities that ship their products into interstate commerce.

The Federal Food, Drug, and Cosmetic Act (the Act)(21 U.S.C. 321(f), defines food as “(1) articles used for food or drink for man or other animals...and (3) articles used for components of any such article.” (Section 201(f)). Food-producing animals and fish, even though not in their final, edible form, have been held to be food under the statute United States v. Tomahara Enterprises Ltd., Food Drug Cosm. L. Rep. (CCH) 38,217 (N.D.N.Y. 1983) (live calves intended as veal are food) and United States v. Tuent Livestock, 888 F. Supp. 1416, 1423-26 (S.D. Ohio 1995) (live hogs are food). More generally, courts have long held that unprocessed or unfinished articles are or can be food. See Otis McAllister & Co. v. United States, 194 F.2d 386, 387 (5th Cir. 1952) and cases cited there (unroasted coffee beans are food). Thus, live animals raised for food are “food” under the Act.

Regulatory action can be taken against a producer or other responsible persons when it has been documented that the animals offered for slaughter in interstate commerce resulted in illegal residue(s) in edible tissue. [21 U.S.C. 331(a)] For example, regulatory action can be taken against a producer who sells animals containing illegal drug residues to an intermediate party, which in turn sells them at

an auction, where they are purchased by a buyer who in turn sells them to a slaughter plant doing an interstate business. In such circumstances the producer can be charged with causing the delivery for introduction into interstate commerce of adulterated food, even if the producer has no specific knowledge of the ultimate destination of the animals.

The other parties involved in the scenario may also be charged with causing the delivery for introduction into interstate commerce of adulterated food, or they may be charged with offering for introduction into interstate commerce. Additionally, "caused to be introduced" charges may be brought against veterinarians, animal dealers, buyers, vendors, auction barns, or other persons who are responsible for having caused the residue or having introduced animals into interstate commerce without first assuring that the animals were free of illegal residues [21 U.S.C. 331(a)]

When treated animals remain on the premises, initiate action to prevent further processing of the animals, such as requesting that USDA/FSIS sample and hold future shipments made by the producer and/or requesting State detention/quarantine of the animals. Provide complete information (e.g., suspected shipment date, destination, drugs involved, etc.) to cooperating agencies and officials.

B. INITIAL VIOLATION

The FSIS Violation Notification Letter includes appropriate language to serve as FDA prior warning to the producer shipping animals with violative residues. Under the following circumstances it is appropriate to issue a Warning Letter to an initial violator (when the investigation confirms his culpability):

- Involvement of drugs considered of **high risk to human** health/safety whether approved or unapproved.
- Involvement of apparent extra-label use. Refer to 21 CFR Part 530.
- The occurrence of residue levels so high as to indicate intentional misuse of the drug
- Involvement of drugs where no tolerance has been established.

Seafood violations: All drugs for which seafood is currently tested are not approved for any food fish use in the United States. If the violation, jurisdiction, and responsibility can be documented, CVM would consider a Warning Letter for the initial violation.

C. REPEAT/MULTIPLE VIOLATIONS

DATE OF ISSUANCE: August 1, 2005
 MINOR CORRECTIONS: August 23, 2005
 FORM FDA 2438

Firms or individuals who repeatedly present adulterated animals for slaughter may represent a significant public health risk.

1. Warning Letter

A Warning Letter should be considered as a follow-up to a repeat violation. See Attachment B for model Warning Letters. Warning Letters for tissue residue violations may be issued directly by the District Director except those concerning tissue residue violations where no tolerance has been established, extra-label use is documented, and/or those which involve the use of compounded drugs or other drug adulteration. Warning Letters for aquaculture and other animal-derived products also require CVM concurrence prior to issuance. The exceptions listed above require CVM concurrence prior to issuance.

Warning Letters must be submitted to CVM no later than 8-10 weeks from the date of **last evidence collection** to meet Agency timeframes. In the past the regulatory time clock has routinely started on the date of investigation/inspection of the animal producer. However, since residue investigations frequently require additional time-consuming visits to fully document the violation, it is important to include dates of visits made to the veterinarian, auction barn, dealer, slaughter house, etc. in your recommendation to CVM. Include language in the Warning Letter that clearly specifies the beginning and end dates of the investigation.

Title 18 violations may also be included in the Warning Letter to inform the recipient that GIPSA or FSIS may take actions against these violations. (See Attachment E). These are circumstances where false certificates or guarantees are knowingly provided or when provided without any knowledge of the animal's medication status. Do not issue Warning Letters containing only Title 18 violations.

If the state inspection documents residue violation, responsibility, and jurisdiction, CVM will consider Warning Letter recommendations based on the state inspectional data.

2. Injunction

If a tissue residue violation(s) **occurs after the** issuance of a Warning Letter then injunction should be considered against a producer and/or other parties that are responsible for introducing animals into interstate commerce that result in illegal residues. As with most injunctive actions, we need a history of violations and a good description of scope and size of the violator's operation to help explain the need for court action to achieve compliance. Contact FSIS to initiate intensive sampling of the producer's animals. The injunction will be reviewed concurrently with the effort to obtain any additional documented violations. In order to proceed with a preliminary injunction a documented violative residue or, if it involves a

producer, an FDA inspection, no older than 60 days is required. If the 60-day time frame cannot be met, consider proceeding with a permanent injunction. If another residue violation occurs after a consent decree has been signed, and the inspection documents a violation, responsibility, and jurisdiction, the District should contact the Office of General Counsel (OGC) attorney who handled the original consent decree to discuss enforcement options. In the absence of the original attorney please contact Eric Blumberg, GCF-1 for further advice.

3. Prosecution

Prosecution may be considered when the residue violations involve one or more of the following elements and the individuals knowingly do or use:

- Drugs not permitted for extra-label use in food animals, banned or unapproved drugs that present significant human health safety concerns.
- Blatant misuse of toxicologically significant drugs resulting in residues substantially above tolerance.
- Issuing false guarantees that animals with violative residues were drug-free or had been properly withdrawn from the drug(s).
- Multiple misdemeanor counts and/or one or more felony counts.

The Office of Criminal Investigations (OCI) is responsible for reviewing all matters in FDA for which a criminal investigation is recommended, and is the focal point for all criminal matters.

FDA personnel must refer all criminal matters, regardless of their complexity or breadth, to OCI. This includes criminal search warrants, misdemeanor prosecutions, felony prosecutions, referrals for criminal investigation, and Section 305 meetings.

District management must communicate with its local OCI office before pursuing any criminal matter. This communication is absolutely essential to preclude potential interference with other on-going criminal investigations and to prevent confusion among the components of the Office of Chief Counsel and the Department of Justice that are responsible for handling FDA's criminal cases. During this communication, OCI is to be provided with all of the facts of the potential case and any additional information that is relevant to, or could impact, the case in any way. OCI will decide promptly whether or not it is interested in pursuing the case and will communicate its decision back to the District Office.

If OCI chooses not to pursue a criminal matter, the District Office is at liberty to proceed with the case in accordance with the procedures in Chapter 6 of the Regulatory Procedures Manual.

PART VI - CONTACTS, ATTACHMENTS, AND REFERENCES

A. PROGRAM CONTACTS

1. CVM

a. Program Inquiries

Deborah Cera, Program Manager
240-276-9209
Compliance Information Management Team, HFV-235
CVM/Division of Compliance
Deborah.cera@fda.hhs.gov

b. Technical Guidance

Frances Pell, 240-276-9211 or Deborah Cera, 240-276-9209
Compliance Information Management Team, HFV-235
CVM/Division of Compliance, HFV-235
Deborah.cera@fda.hhs.gov
Frances.pell@fda.hhs.gov

c. Regulatory Inquiries

Reginald Walker
240-276-9234
Enforcement and Regulatory Policy Team, HFV-232
CVM/Division of Compliance
Reginald.walker@fda.hhs.gov

d. Policy Questions

Gloria Dunnavan, Director
240-276-9200
CVM/Division of Compliance, HFV-230
Gloria.dunnavan@fda.hhs.gov

2. ORA

a. Inspectional Inquiries

Division of Field Investigations, HFC-132,
Telephone: Jim Dinnie, 301-827-5652

b. Analytical Inquiries

Division of Field Science, HFC-141,
Telephone: George Salem, 301-827-1031

c. Federal/State Relations Inquiries

Division of Federal-State Relations, HFC-152
Telephone: Glenn Johnson, 301-827-2907

B. LIST OF ATTACHMENTS

1. Attachment A - FSIS Laboratory Reporting Codes
2. Attachment B- Model Letters
3. Attachment C- Tissue Residue Evaluation Form
4. Attachment D - USDA Contacts
5. Attachment E - GIPSA/Title 18 Memo
6. Attachment F - Example of Slaughter Plant Affidavits
7. Attachment G - Drug Inventory Survey
8. Attachment H – Program Monitor Checklist

C. APPLICABLE REFERENCES OR AIDS

1. INVESTIGATIONS OPERATIONS MANUAL (IOM): Chapters 4 & 5 Sampling and Inspection.
2. 21 CFR Parts 500-599, Animal Drugs, Feeds, and Related Products.
3. [Compliance Policy Guides:](#)
 - Sec. 608.400 - Compounding of Drugs for Use in Animals. (CPG 7125.40)
 - Sec. 615.300 - Responsibility for Illegal Drug Residues in Meat, Milk and Eggs. (CPG 7125.05)
 - Sec. 608.100 - Human-Labeled Drugs Distributed and Used in Animal Medicine. (CPG 7125.35)
 - Sec. 615.200 - Proper Drug Use and Residue Avoidance by Non-Veterinarians. (CPG 7125.37)
 - Sec. 615.115 - Extra-label Use of Medicated Feeds for Minor Species
4. Compliance Programs
 - 7303.039 National Drug Residue Milk Monitoring Program
 - 7371.002 Illegal Sales of Veterinary Prescription Drugs
 - 7371.003 Feed Contaminants
 - 7371.004 Feed Manufacturing
 - 7304.018 Chemotherapeutics in Seafood Compliance Program
5. [Regulatory Procedures Manual.](#)
6. AOAC Official Methods of Analysis, 16th Edition.
7. Memorandum of Understanding - MOU 225-85-8400 - Memorandum of Understanding between FDA, FSIS and EPA.

PART VII - CVM RESPONSIBILITIES

A. Program Evaluation

Information extracted from Attachment C Evaluation Forms will be entered into TRIMS (Tissue Residue Information Management System). This database will facilitate the management and analysis of information related to tissue residue violations.

The Compliance Information Management Team will periodically prepare reports of program findings.

B. Inter-Center Action

The Compliance Information Management Team will coordinate CVM efforts to exchange residue data with the Center for Food Safety and Applied Nutrition, especially when the data may indicate a potential for residues in seafood, milk, and/or eggs.

C. Compliance Information Management Team

The Compliance Information Management Team has the primary responsibility for managing/coordinating FDA-related tissue residue activities.

Significant functions include the following:

- To serve as the primary contact between the FDA District Tissue Residue Monitors and CVM; the objective is to exchange information and provide guidance on residue-related issues and to respond to any problems/needs the Field identifies.
- To identify, recommend, develop, and implement preventive measures to reduce the number violative residues.
- To prioritize work efforts for program-related resources.
- To identify specific residue/violator trends through the Residue Violation Information System (RVIS) and the Tissue Residue Information Management System (TRIMS).
- To provide CVM's Division of Compliance and the Field with relevant residue information to support enforcement actions.
- To coordinate all FDA efforts concerning the RVIS.
- To serve as the primary contact point between FDA and FSIS in an effort to provide meaningful input into the development and implementation of the National Residue Program for meat and poultry.

- To serve as the primary contact point between FDA's CVM and CFSAN to provide input into the development and implementation of drug residue testing programs.

D. Enforcement and Regulatory Policy Team

CVM's Enforcement and Regulatory Policy Team is responsible for the review of all CVM-related enforcement actions and can frequently help in determining the responsible parties. It can also provide guidance on the proper collection of the analytical, investigational, and other evidence needed to support a case. For questions involving case development, please contact the Enforcement and Regulatory Policy Team, HFV-232, Reginald Walker for assistance.

**ATTACHMENT A – USDA REPORTING CODES
FSIS/USDA Laboratory Reporting Codes**

<u>USDA Residue</u>	<u>USDA Residue Name</u>
0	CAST GENERAL
1	RESIDUE-ACTUAL SPIKED AMOUNT
30	AFLATOXIN
50	NITROSAMINES
51	N-NITROSADIMETHYLAMINE
52	N-NITROSADIETHYLAMINE
53	N-NITROSODIPROPYLAMINE
54	N-NITROSODIBUTYLAMINE
55	N-NITROSOPIPERDINE
56	N-NITROSOPYRROLIDINE
57	N-NITROSOMORPHOLINE
59	RECOVERY
60	CYANIDE
61	STYRENE
80	SYNTHETIC PYRETHRINS
81	CYPERMETHRIN
82	DELTAMETHRIN
83	FENVALERATE
84	FLUCYTHRINATE
85	PERMETHRIN
86	NATURAL PYRETHRINS
87	PYRETHRIN I
88	PYRETHRIN II
89	CINERIN I
90	CINERIN II
92	PIPERONYL BUTOXIDE
99	OTHER
100	HALOCARBON PESTICIDES
101	ALDRIN
102	BENZENE HEXACHLORIDE

USDA Residue**USDA Residue Name**

103	CHLORDANE
104	DIELDRIN
105	DDT AND METABOLITES
106	ENDRIN
107	HEPTACHLOR AND METABOLITES
108	LINDANE
109	METHOXYCHLOR
110	TOXAPHENE
111	PCB'S
112	HEXACHLOROBENZENE
113	MIREX
114	STROBANE
115	NONACHLOR
116	OCTACHLORO DIBENZODIOXIN
117	HEPTACHLORO DIBENZODIOXIN
118	HEXACHLORO DIBENZODIOXON
119	TETRACHLORO DIBENZODIOXIN
120	DICHLOROPHENOL
121	TRICHLOROPHENOL
122	TETRACHLOROPHENOL
123	PENTACHLOROPHENOL
124	P,P-DDT
125	O,P-DDT
126	P,P-DDE
127	O,P-DDE
128	P,P-TDE
129	O,P-TDE
130	UNIDENTIFIED RET REL TO 101
131	UNIDENT PEAK 1 RETN REL TO 101
132	UNIDENT PEAK 2 RETN REL TO 101
133	UNIDENT PEAK 3 RETN REL TO 101
134	UNIDENT PEAK 4 RETN REL TO 101
135	UNIDENT PEAK 5 RETN REL TO 101
136	UNIDENT PEAK 6 RETN REL TO 101

USDA Residue**USDA Residue Name**

137	UNIDENT PEAK 7 RETN REL TO 101
138	UNIDENT PEAK 8 RETN REL TO 101
139	UNIDENT PEAK 9 RETN REL TO 101
140	UNIDENTIFIED RET AMT TO 101
141	UNIDENT PEAK 1 AMT REL TO 101
142	UNIDENT PEAK 2 AMT REL TO 101
143	UNIDENT PEAK 3 AMT REL TO 101
144	UNIDENT PEAK 4 AMT REL TO 101
145	UNIDENT PEAK 5 AMT REL TO 101
146	UNIDENT PEAK 6 AMT REL TO 101
147	UNIDENT PEAK 7 AMT REL TO 101
148	UNIDENT PEAK 8 AMT REL TO 101
149	UNIDENT PEAK 9 AMT REL TO 101
150	KEPONE
161	PARA-DICHLORO-BENZENE
162	TETRACHLOROETHYLENE
163	HEPTACHLOR - CHECK SAMPLE REPORTING
164	HEPTACHLOR EPOXIDE - CHECK SAMPLE REP.
181	HALOWAX
191	PBB
192	ETHYLENEDIBROMIDE
193	METHYLBROMIDE
200	ANTIBIOTICS
201	PENICILLIN
202	STREPTOMYCIN

USDA Residue**USDA Residue Name**

203	CHLORAMPHENICOL
204	TETRACYCLINE
205	TYLOSIN
206	ERYTHROMYCIN
207	NEOMYCIN
208	OXYTETRACYCLINE
209	CHLORTETRACYCLINE
210	UNIDENTIFIED MICROBIAL INHIBITOR
211	GENTAMICIN
212	LINCOMYCIN
213	CLOXACILLIN
214	APRAMYCIN
215	AMOXICILLIN
216	NOVOBIOCIN
217	SPECTINOMYCIN
218	VIRGINIAMYCIN
298	TETRACYCLINES (INJECTION SITE)
299	SWAB POSITIVE-BIOASSAY NEGATIVE
300	ORGANIC PHOSPHORUS PESTICIDES
301	COUMAPHOS AND OXYGEN ANALOG
302	DICHLORVOS
303	DIAZINON
304	ETHION AND OXYGEN ANALOG
305	MALATHION
306	PARATHION
307	RONNEL
308	CRUFOMATE
309	TRICHLORFON
310	METHYL PARATHION
311	DIOXATHION
312	DISULFOTON
313	FENETHROTHION
314	STIROFOS (OR TETRACHLORINPHOS)
315	CHLOPYRIFOS
316	FENTHION

USDA Residue**USDA Residue Name**

318	CARBOPHENTHION (TRITHION R)
319	AZINPHOS-METHYL (GUTHION R)
320	CHLORFENVINPHOS
330	UNIDENTIFIED RET REL TO 306
331	UNIDENT PEAK 1 RETN REL TO 306
332	UNIDENT PEAK 2 RETN REL TO 306
333	UNIDENT PEAK 3 RETN REL TO 306
334	UNIDENT PEAK 4 RETN REL TO 306
335	UNIDENT PEAK 5 RETN REL TO 306
336	UNIDENT PEAK 6 RETN REL TO 306
337	UNIDENT PEAK RENT REL TO 306
340	UNIDENTIFIED RET AMT TO 306
341	UNIDENT PEAK 1 AMT REL TO 306
342	UNIDENT PEAK 2 AMT REL TO 306
343	UNIDENT PEAK 3 AMT REL TO 306
344	UNIDENT PEAK 4 AMT REL TO 306
345	UNIDENT PEAK 5 AMT REL TO 306
346	UNIDENT PEAK 6 AMT REL TO 306
347	UNIDENT PEAK 7 AMT REL TO 306
360	CHLORINATED ORGANIC PHOSPHORUS
361	ETHION METABOLITE
362	COUMAPHOS METABOLITE
363	CHLORPYRIFOS METABOLITE
370	ORGANIC PHOSPHORUS COMPOUNDS
371	2-ETHYLHEXYLDIPHENYL PHOSPHATE
400	ARSENIC
401	ARSENIC
402	MERCURY
403	COPPER
404	LEAD
405	ZINC
406	CADMIUM
407	ANTIMONY
408	SELENIUM
409	ALUMINUM

<u>USDA Residue</u>	<u>USDA Residue Name</u>
410	TITANIUM
411	IRON
412	NICKLE
413	COBALT
414	MANGANESE
415	CHROMIUM
416	TIN
417	SODIUM
418	PHOSPHORUS
419	CALCIUM
420	POTASSIUM
421	MAGNESIUM
500	HORMONES
501	DIETHYLSTILBESTROL
502	DIENESTROL DIACETATE
503	ESTRADIOL BENZOATE
504	MELENGESTROL ACETATE
505	PROGESTERONE
506	TESTOSTERONE
508	MEDROXYPROGESTERONE ACETATE
509	CHLOMADINONE ACETATE
510	ZEARALANOL (ZERANOL)
511	ESTRADIOL MONOPALMITATE
512	HEXESTROL
513	ZEARALENONE
514	TALERANOL
600	CARBAMATES
601	CARBARYL
602	ALDICARB & METABOLITES SULFOXIDE & SULFO
604	PROPOXUR
605	CARBOFURAN AND 3 HYDROXYCARBOFURAN
606	METHIOCARB AND ITS METABOLITE SULFOXIDE
607	BUFENCARB

<u>USDA Residue</u>	<u>USDA Residue Name</u>
608	METHOMYL
615	THIRAM
620	LARVICIDE
621	CYROMAZINE
622	MELAMINE
650	NITROGEN PESTICIDES
651	CARBOXIN
652	AMITRAZ
700	HERBICIDES
701	2,4,-D
702	2,4,5-T
703	METHNEARSONIC ACID
710	TRIAZINE
711	PROMETON
712	PROPAZINE
713	TERBUTYLAZINE
714	ATRAZINE
715	PROMETRYN
716	TERBUTRYN
717	SIMAZINE
718	AMETRYN
800	SULFAS
801	SULFAETHOXYPYRIDAZINE
802	SULFACHLORPYRIDAZINE
803	SULFADIMETHOXINE
804	SULFANITRAN
805	SULFAMETHAZINE
806	SULFACHLOROPYRAZINE
807	SULFAMETHOXYPYRIDAZINE
808	SULFAMERAZINE
809	SULFATHIAZOLE
810	SULFAQUINOXALINE
811	SULFABROMOMETHAZINE
812	SULFAMETHIZOLE
813	SULFANILAMIDE

USDA Residue**USDA Residue Name**

814	SULFAPYRIDINE
815	SULFADIAZINE
816	SULFADOXENE
830	UNIDENTIFIED RET REL TO 814
831	UNIDENT PEAK 1 RETN REL TO 814
832	UNIDENT PEAK 2 RETN REL TO 814
840	UNIDENTIFIED RET AMT TO 814
841	UNIDENT PEAK 1 AMT REL TO 814
842	UNIDENT PEAK 2 AMT REL TO 814
900	DRUGS, GENERAL
901	CLOPIDOL
902	FURAZOLIDONE
903	NITROFURAZONE
904	DECOQUINATE
905	MONENSIN
906	IPRONIDAZOLE
907	CARBADOX
908	ROBENIDINE
910	LEVAMISOLE
911	DIMETRIDAZOLE
912	GENTIAN VIOLET
913	DIBUTYLTINDILAUATE
914	LYSERGIC ACID DIETHYLAMIDE
915	PHENCYCLIDINE
916	XYLAZINE
917	LASALOCID
918	NARASIN
921	MORANTEL TARTRATE
922	PYRANTEL TARTRATE
923	IVERMECTIN
924	ARSENIC (DRUGS)
926	HALOFUGINONE
927	CLORSULON
931	UNIDENT PEAK 1 RETN REL TO 2
932	UNIDENT PEAK 2 RETN REL TO 2

USDA Residue

USDA Residue Name

941	UNIDENT PEAK 1 AMT REL TO 29
942	UNIDENT PEAK 2 AMT REL TO 29
950	BENZIMIDAZOLES
951	ALBENDAZOLE
952	FENBENDAZOLE
953	THIABENDAZOLE & METABOLITE
954	MEBENDAZOLE
955	OXFENDAZOLE

USDA TISSUE LOOK-UP TABLE

<u>Code</u>	<u>Name</u>	<u>Code</u>	<u>Name</u>
01	Fat	37	Cheeks
02	Liver	38	Cloaca
03	Muscle	39	Colon
04	Kidney	40	Comminuted Meat
06	Other	41	Corpus Luteum
07	Lung	42	Crop
08	Lymph Node	43	Ductus Deferens
09	Heart	44	Duodenum
10	Skin	45	Ears
11	Spleen	46	Epididymis
12	Brain	47	Esophagus
13	Eye or Eye Lesion	48	Feather
14	Peritoneum	49	Feather Follicle
15	Nerve	50	Fur
16	Bursa Fabricius	51	Gall Bladder
17	Adrenal Gland	52	Ganglion
18	Abdomen	53	Gizzard
19	Abomasum	54	Gray Matter
20	Air Sacs	55	Hair
21	Alveolar Duct	56	Hemal Node
22	Alveolar Sac	57	Hock
23	Alveoli	58	Hoof
24	Aorta	59	Horn
25	Artery	60	Intestinal Glands
26	Blood Vessel	61	Joint
27	Bone	62	Large Intestine
28	Bronchi	63	Larynx
29	Bronchioles	64	Leg
30	Cardiac Tissue	65	Lips
31	Cartilage	66	Lymphatic
32	Cecum	67	Lymph Vessel
33	Cerebellum	68	Mammary Gland
34	Cerebrum	69	Mesentery
35	Ceruminous Glands		
36	Cervix		

USDA TISSUE LOOK-UP TABLE

<u>Code</u>	<u>Name</u>	<u>Code</u>	<u>Name</u>
70	Mouth	98	Thigh
71	Neck	99	Thorax
72	Nose	A1	Thymus
73	Omasum	A2	Thyroid Gland
74	Omentum	A3	Tongue
75	Ovary	A4	Tooth
76	Palate	A5	Trachea
77	Pancreas	A6	Tumor Mass
78	Parathyroid	A7	Ureter
79	Penis	A8	Urinary Bladder
80	Peripheral Nerve	A9	Uterine Horn
81	Phalanges	B1	Uterus
82	Pineal Gland	B2	Vagina
83	Pituitary Gland	B3	Vein
84	Placenta	B4	Ventriculus
85	Prostate Gland	B5	Villi
86	Proventriculus	B6	Vulva
87	Reticulum	B7	White Matter
88	Rectum	B8	Intestine
89	Rumen	B9	Blood Smears
90	Salivary Gland	C1	Oviduct
91	Sebaceous Gland	C2	Keel Bursa
92	Seminal Vesicle	C3	Blood
93	Small Intestine	C4	Serum
94	Spinal Cord	C5	Diaphragm
95	Stomach	C6	Parasite
96	Testis	C7	Multiple Specimens
97	Tissue Mass	C8	Plant Mat. - Soya

USDA TISSUE LOOK-UP TABLE

<u>Code</u>	<u>Name</u>	<u>Code</u>	<u>Name</u>
D1	Secretory Glands		
D2	Plant Fiber		
D3	Urine		
D4	Kidney B		
D5	Serum A		
D6	Serum B		
D7	Bile		
D8	Tailhead Fat		
D9	Brisket Fat		
E1	Hard Bone		
E2	Soft Bone		
E3	Eggs		
E4	Milk		
E5	Colostrum		
E6	Fatty Tissue		
E7	Saliva		
E8	Condensate		
E9	Feed		
F1	Edible Proc. Product		
U3	Urine		

MARCIS SPECIES CODES ON USDA RECORDS

<u>Code</u>	<u>Name</u>	<u>Code</u>	<u>Name</u>
00	Non-Species	51	Market Hog
01	Horse	52	Boar or Stag
10	Bovine	53	Sow
11	Bull	59	Other Red Meat
12	Steer	60	Chicken
13	Beef Cow	61	Young Chicken
14	Heifer	63	Mature Chicken
15	Dairy Cow	70	Turkey
20	Calf	71	Fry Roast Turkey
21	Bob Veal	72	Young Turkey
22	Formula Fed Veal	73	Mature Turkey
23	Non-formula Fed Veal	81	Duck
24	Heavy Calves >400 lbs.	82	Geese
30	Sheep	91	Rabbit
31	Mature Sheep	92	Deer
32	Lamb	97	Blank
40	Goat	98	Blank
50	Porcine	99	Other

SPECIES/ANIMAL LOOK-UP TABLE USED BY USDA

Species #	Species Name	Animal #	Animal Name
1	EQUINE	1	HORSE
10	CATTLE	10	COWS
		11	BULLS/STAGS
		12	STEERS
		13	COWS - BEEF
		14	HEIFERS
		15	COWS - DAIRY
20	CALVES	20	CALVES
		21	BOB - VEAL
		22	FORMULA FED VEAL
		23	NON FORMULA FED VEAL
		24	HEAVY CALVES
30	SHEEP	30	SHEEP
		31	MATURE SHEEP
		32	LAMBS & YEARLINGS
40	GOATS	40	GOATS
50	SWINE	50	SWINE
		51	BARROWS & GILTS / MARKET HOGS
		52	BOARS / STAGS
		53	SOWS
		54	ROASTER PIGS
59	OTHER	58	WATER BUFFALO
		59	OTHER (BUFFALO, ETC.)
		99	OTHER ANIMAL
60	CHICKENS	60	CHICKENS
		61	YOUNG CHICKENS
		63	MATURE CHICKENS
70	TURKEYS	70	TURKEYS
		71	FRYER ROASTER
		72	YOUNG TURKEY
		73	MATURE TURKEY
80	DUCKS	81	DUCKS
		82	GEESE
		84	QUAIL
90	RATITE	83	OSTRICH
		85	EMU
		86	RHEA
91	RABBITS	91	RABBITS
92	DEER	92	DEER

**ATTACHMENT B-1
SAMPLE PRODUCER WARNING LETTER
(or for other individual administering medication)**

[date]

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

OR Federal Express

RESPONSIBLE INDIVIDUAL(S), TITLE (S)

FIRM NAME

RESPONSIBLE INDIVIDUAL'S COMPLETE MAILING ADDRESS

WARNING LETTER

(#)

Dear [Name]:

An investigation of your [dairy, swine raising, etc.] operation located at [inspected facility's physical address (if different from mailing address)], conducted by a representative of the U.S. Food and Drug Administration (FDA) on [inspection dates (including the last date of evidence collection)], confirmed that you offered (an) animal(s) for sale for slaughter as food that was adulterated under sections 402(a)(2)(C)(ii) [21 U.S.C. 342 (a)(2)(C)(ii)] and 402(a)(4) [21 U.S.C. 342 (a)(4)] of the Federal Food, Drug, and Cosmetic Act (the Act). The inspection also revealed that you caused the [new animal drug(s)] [medicated feed(s)] [trade name or generic name of drug(s) or feed(s)] to become adulterated within the meaning of section [501(a)(5)] [21 U.S.C. 351(a)(5)] [501(a)(6)] [21 U.S.C. 351(a)(6)] and unsafe under section 512 of the Act [21 U.S.C 360b]. You can find the Act and its associated regulations on the Internet through links on the FDA's web page at www.fda.gov.

On or about [date], you [sold] [consigned] a [identify animal/species], identified with [provide some form of man made identification to appropriately identify the animal] for slaughter as food at [name of slaughterhouse]. On or about [date] this animal was slaughtered at [name of slaughterhouse]. United States Department of Agriculture, Food Safety and Inspection Service (USDA/FSIS) analysis of tissue samples collected from that animal identified the presence of [level and name of drug(s) for each tissue(s) in which (an) illegal residue(s) (was)/(were) reported]. [No tolerance] [A tolerance of (level)] has been established for residues of [name of drug(s)] in the edible tissues of [type of animal][.] as codified in Title 21, Code of Federal Regulations, Part 556.# (21

C.F.R. 556.#). The presence of [this]/[these] drug(s) in edible tissue(s) from this animal causes the food to be adulterated within the meaning of section 402(a)(2)(C)(ii) [(21 U.S.C. § 342(a)(2)(C)(ii)].

[For three or more residues you may want to develop a table for clarification]

Our investigation also found that you hold animals under conditions that are so inadequate that medicated animals bearing potentially harmful drug residues are likely to enter the food supply. You lack an adequate system to ensure that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. For example, [you failed to maintain treatment records] [you failed to maintain complete treatment records] [you failed to segregate treated animals] [you lack an adequate inventory system for determining the quantities of drugs used to medicate your animal(s)] **[etc.]**. Food from animals held under such conditions is adulterated within the meaning of section 402(a)(4) of the Act [21 U.S.C. 342 (a)(4)].

In addition, you adulterated [name of drug(s)] within the meaning of section 501(a)(5) [21 U.S.C. 351 (a)(5)] of the Act when you failed to use the drug in conformance with its approved labeling. "Extralabel use," i.e., the actual or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling, is only permitted if the use is by or on the lawful order of a licensed veterinarian within the context of a valid veterinarian/client/patient relationship. The extralabel use of approved veterinary or human drugs must comply with sections 512(a)(4) and 512(a)(5) of the Act and 21 C.F.R. Part 530. Our investigation found that your extralabel use of [name of drug(s)] failed to comply with these requirements.

For example, you administered the [name of drug(s)] without following the [dosage level] [duration of treatment] [frequency of treatment] [withdrawal period] [in the approved animal class or species] **[other appropriate items]** set forth in the approved labeling and you did so without the supervision of a licensed veterinarian, in violation of 21 C.F.R. 530.11(a). Furthermore, your extralabel use resulted in an illegal drug residue, in violation of 21 C.F.R. 530.11(c). Because your extralabel use of this drug was not in compliance with 21 CFR Part 530, the drug was unsafe under section 512(a) of the Act [21 U.S.C. 360b(a)] and your use caused it to be adulterated within the meaning of section 501(a)(5) of the Act [21 U.S.C. 351(a)(5)].

In addition, you adulterated [name of medicated feed(s)] within the meaning of section 501(a)(6) of the Act [21 U.S.C. 351(a)(6)] when you failed to use the drug in conformance with its approved labeling. Your use of this [medicated feed(s)] without following the [dosage level] [duration of treatment] [frequency of treatment] [withdrawal period] [in the approved animal class or species] **[other appropriate items]** set forth in the approved labeling causes this drug to be unsafe within the meaning of section 512 of the Act [21 U.S.C. 360b]. Section 512 does not permit the extralabel use of medicated feeds.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for ensuring that your overall operation and the food you distribute is in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

You should notify this office in writing of the steps you have taken to bring your firm into compliance with the law within fifteen (15) working days of receiving this letter. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your written response should be sent to [name], Compliance Officer, U.S. Food and Drug Administration, [mailing address]. If you have any questions about this letter, please contact Compliance Officer [name] at [phone, fax, Email, mailing address].

Sincerely yours,

[name]

District Director

[name] District

cc: Additional Responsible Individual(s)

State Regulatory Authority

Producer's Servicing Veterinarian

bcc: HFA-224

HFC-210

HFC-230

HFV-230

HFV-235

HFV-2__ (Center CSO reviewer)

HFI-35 (purged)

ATTACHMENT B-2

**SAMPLE WARNING LETTER
EXTRA-LABEL DRUG USE by VETERINARIAN**

[Date]

WARNING LETTER

Ref:

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Responsible Individual, Title
Firm Name
Firm's Complete Address

Dear Dr. _____;

On (dates), an investigator from the U.S. Food and Drug Administration (FDA) conducted an investigation involving the use of drugs in your veterinary practice. That investigation revealed that you caused animal drugs to be unsafe under Section 512(a) of the Federal Food, Drug, and Cosmetic Act (the Act) and adulterated within the meaning of Section 501(a)(5) of the Act because the drugs were used in a manner that did not conform with their approved uses or the regulations for Extralabel Drug Use in Animals, Title 21, Code of Federal Regulations (21 CFR), Part 530.

The extralabel use of approved veterinary or human drugs in animals is permitted only if it complies with Sections 512(a)(4) and 512(a)(5) of the Act and 21 CFR Part 530. Our investigation found that you failed to comply with 21 CFR Part 530 in that:

1. You used the drug (trade name) brand of (generic name) in an extralabel manner by administering the drug intravenously to (type of animal). The extralabel use of this drug in this animal is prohibited by 21 CFR Part 530.41(a)(9). Approved uses of such drugs are listed in 21 CFR Part 520.2220a, copy enclosed.
2. You used the drug (trade name) brand of (generic name) in an extralabel manner by administering the drug to (type of animal) without meeting the requirements of 21 CFR Part 530. For example, in the treatment of this animal, milk discard and meat withdrawal periods were not established as required by 21 CFR Part 530.20(a)(2)(ii).
3. You prescribed the intravenous administration of the injection form of the drug (trade name) brand of (generic name) to treat pneumonia in lactating dairy cattle. This is an extralabel use. Approved uses of (generic name) injection are listed in 21 CFR Part 520, copy enclosed. Your prescription

for the extralabel use of this drug did not meet the requirements of 21 CFR Part 530(a)(2)(i)–(iv), which require that you:

- (i) Make a careful diagnosis and evaluation of the conditions for which the drug is to be used;
- (ii) Establish a substantially extended withdrawal period prior to marketing of milk, meat, eggs, or other edible products supported by appropriate scientific information, if applicable;
- (iii) Institute procedures to assure that the identity of the treated animal or animals is carefully maintained; and
- (iv) Take appropriate measures to assure that assigned timeframes for withdrawal are met and no illegal drug residues occur in any food-producing animal subjected to extralabel treatment.

You caused the aforementioned animal drug to be unsafe under Section 512(a) of the Act and adulterated within the meaning of Section 501(a)(5) of the Act because the drugs were prescribed and used in a manner that did not conform with their approved uses or the regulations for Extralabel Drug Use in Animals, 21 CFR Part 530.

The above is not intended to be an all-inclusive list of violations. As licensed veterinarians, you are responsible for complying with the requirements of the Act, including the extralabel use regulations promulgated under the Act. You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

We have enclosed a copy of 21 CFR Part 530 for your reference. We strongly suggest that you review 21 CFR Part 530 and become familiar with all of its requirements so that you can prevent future violations of the Act.

You should notify this office in writing within 15 working days of receiving this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Also, include copies of any available documentation demonstrating that your corrections have been made.

Your reply should be directed to Compliance Officer (name) at the address indicated on the letterhead.

Sincerely,

District Director

cc: State Board of Veterinary Medicine, FSIS TSC, State, HFV-232, etc.

**ATTACHMENT B-3
SAMPLE WARNING LETTER
ILLEGAL DRUG SALE**

[Date]

WARNING LETTER

Ref:

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

FIRM NAME
RESPONSIBLE INDIVIDUAL, TITLE
FIRM'S COMPLETE ADDRESS

Dear _____,

Recently an inspection was made of your veterinary drug distribution facility located at (address). This inspection was conducted on (dates), by a Food and Drug Administration (FDA) investigator from this office, who documented the sales of prescription veterinary drugs, such as (name of drug(s)), without requiring a written prescription or oral order from a licensed veterinarian. Under Section 503(f)(1)(C) of the Federal Food, Drug and Cosmetic Act, the dispensing of a prescription drug other than by or upon the lawful written or oral order of a licensed veterinarian results in the drug being misbranded.

In addition, the prescription drugs dispensed by your firm are misbranded within the meaning of section 502(f)(1) because they lack adequate directions for use. Pursuant to Title 21, Code of Federal Regulations, section 201.5, "adequate directions for use" means adequate directions under which the layman can use a drug safely and for the purposes for which it was intended. Such adequate directions for use by laypersons cannot be written for prescription drugs because the drugs can only be used safely at the direction of, and under the supervision of, a licensed veterinarian.

The corrective action of posting a sign with a list of prescription veterinary drugs that require a veterinarian's prescription does not appear to be adequate. During the inspection of your firm, the FDA Investigator observed your employee selling prescription animal drugs without requiring a written prescription or oral order from a licensed veterinarian. In addition, photographs of your firm's product inventory showed that prescription animal drugs were being held for sale that do not appear on the sign posted by your firm.

You should take prompt action to correct these violations and to establish procedures to prevent their recurrence. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

The violations listed above are not intended to be an all-inclusive list. As a corporate official of this firm, you have a responsibility to ensure that all drugs sold by you or other employees of your firm comply with all state and federal laws.

It is necessary that you take action on this matter now. Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the steps you are taking to correct the problems and bring your firm into compliance with the law. Your response should include each step being taken, or that will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days, please state the reason for delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to the Food and Drug Administration (Attention: Compliance Officer) at the above address. If you have any questions concerning the deficiencies noted, you may contact Compliance Officer (name).

Sincerely,

District Director

**ATTACHMENT B-4
SAMPLE WARNING LETTER
BUYER/DEALER**

[Date]

WARNING LETTER

Ref:

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

RESPONSIBLE INDIVIDUAL, TITLE
FIRM NAME
FIRM'S COMPLETE ADDRESS

Dear _____:

An inspection of your operation located in (City, State), by a Food and Drug Administration investigator on (dates), confirmed a (cow/calf/hog) purchased and sold by you on or about (date), for slaughter for human food to (slaughter house), was in violation of Section 402 (a)(2)(C)(ii) of the Federal Food, Drug, and Cosmetic Act.

USDA/FSIS analyses of tissues collected from that animal disclosed the presence of the drug (level and name of drug for each tissue in which illegal residue was reported). A tolerance of () level ppm has been established for residues of (name of drug) in the edible tissues of (type of animal) Title 21 Code of Federal Regulations Section 556. The presence of this drug in edible tissue from this animal causes the food to be adulterated under Section 402(a)(2)(C)(ii) of the Act.

- If appropriate, include the following:

In addition, USDA has reported the finding of illegal residues in (number) other (type of animals) sold by you and offered for slaughter for human food (list animal, drug, date). Copies of letters from USDA/FSIS notifying you of these residues are attached.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction. The violations listed above are not intended to be an all-inclusive list. It is your responsibility to assure that your operations are in compliance with the law. As a dealer of animals, you are frequently the individual who introduces or offers for introduction into interstate commerce, the adulterated animal. As such, you share the responsibility for violating the Federal Food, Drug and Cosmetic Act. To avoid future illegal residue violations you should take precautions such as:

1. Implementing a system to identify the animals you purchase with records to establish traceability to the source of the animal;
2. Implementing a system to determine from the source of the animal whether the animal has been medicated and with what drug(s); and
3. If the animal has been medicated, implementing a system to withhold the animal from slaughter for an appropriate period of time to deplete potentially hazardous residues of drugs from edible tissue. If you do not want to hold the medicated animal then it should not be offered for human food, and it should be clearly identified and sold as a medicated animal.

If appropriate, include the following:

You should be aware that it is not necessary for you to have personally shipped an animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an animal for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within 15 working days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken, that has been taken, or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to the Food and Drug Administration Attention Compliance Officer.

Sincerely,

District Director

cc: FSIS TSC, State, HFV-232, etc.

ATTACHMENT C - TISSUE RESIDUE EVALUATION FORM

Complete one attachment C for each sample and source investigated. The intent of this document is to compile data for statistical reasons on the drugs causing residues. The document is not a substitute for the Official report. The information for this data collection form should be obtained from your inspection report.

All the information on the Attachment has to be related to the source identified in the section, AName and Address of Owner of Animal from FSIS Warning Letter. If you determine during your inspection that 1) the owner wasn=t correctly identified, or 2) the residue can=t be properly traced back or 3) the investigated source ownership changed, then terminate the inspection per Question #2. You should complete a new Attachment C for each new source investigated.

When completing Attachment C, Question #2, select only **one** answer for either an FDA investigation (A) or a State investigation (B). If B is selected fill in the appropriate 2-letter state code.

Complete questions 9-13 for each residue reported for each sample.

Make sure that you properly relate the source to the sample in RVIS

Send to HFV-235, ATT: Fran Pell

- A complete Attachment C for each source/sample investigated,
- A summary of findings for each investigation
- If the Attachment C (at least the first two pages) is not printed from the system please write the Source ID on the front page of the Attachment

Section 1

BACKGROUND INFORMATION

Automatically obtained from RVIS, appropriate entries will be printed

FSIS Sample Number Initiating Investigation:	FSIS Sample Collection Date of Report Initiating Investigation:	FSIS Warning Letter Date:	FSIS Case Number:

CONCENTRATION OF RESIDUE(S) IN TISSUES AS REPORTED BY FSIS:

(Note: For the case of multiple animals per source the option to select and print more than one animal's sample data will be programmed)

ANIMAL: FSIS SAMPLE FORM NO. _____
ANIMAL SPECIES _____

RESIDUE	TISSUE	CONCENTRATION

NAME AND ADDRESS OF OWNER OF ANIMAL FROM FSIS WARNING LETTER:

Name	Address	City	County	State	Zip

SOURCE ALSO KNOWN AS:

Name	Address	City	County	State	Zip

INSPECTIONS ATTRIBUTED TO THIS SOURCE:

	FSIS sample #	Collection Date	Residue	FSIS Letter Date	Investigation Date
A					
B					
C					

Section 2

Please answer the following as completely as possible:

- 1. WERE THE NAME AND ADDRESS OF THE ANIMAL OWNER IDENTIFIED ABOVE BY USDA SPELLED AND LISTED CORRECTLY?**

YES (go to 2)/ NO (if No, ask District Program Monitor to make corrections in RVIS and to notify appropriate FSIS personnel.)

THE INVESTIGATION

(Questions 2-8)

- 2. TYPE OF INVESTIGATION CONDUCTED IN RESPONSE TO CURRENT FSIS RESIDUE REPORT (circle one letter):**

A. FDA INVESTIGATION (complete 1 or 2 below)

B. STATE _____ (enter 2-letter state code) or:

(circle one number for either A or B):

1. On-Site Inspection (Complete Remainder of Report).
2. Inspection Terminated Due to:
 - a. Unable to locate source or traceback
 - b. Investigated sources ownership changed
 - c. Incorrect source identified by USDA
 - d. Other

- 3. DATE INVESTIGATION/INSPECTION COMPLETED:**

__ / __ / __
m m d d y y

- 4. DID THE OWNER IDENTIFIED AT SLAUGHTER ADMIT TO TREATING OR AUTHORIZING THE TREATMENT OF THIS ANIMAL/HERD/FLOCK...? YES / NO**

- 5. LIST THE FOLLOWING INFORMATION FOR ALL INDIVIDUALS / ORGANIZATIONS WHO HANDLED THE ANIMAL / HERD / FLOCK...WITHIN THREE MONTHS PRIOR TO THE SLAUGHTER DATE ?**

<u>Name</u>	<u>Address</u>	<u>Date Animal Acquired</u>	<u>Date Animal Disposed of</u>
A. _____	_____	__ / __ / __	__ / __ / __
	_____	m m d d y y	m m d d y y

firm type(i.e. dealer, hauler) _____

Reason for Acquisition _____

Reason for Disposition _____

B. _____ --/--/-- --/--/--
_____ m m d d y y m m d d y y

firm type(i.e. dealer, hauler) _____

Reason for Acquisition _____

Reason for Disposition _____

C. _____ --/--/-- --/--/--
_____ m m d d y y m m d d y y

firm type(i.e. dealer, hauler) _____

Reason for Acquisition _____

Reason for Disposition _____

D. _____ --/--/-- --/--/--
_____ m m d d y y m m d d y y

firm type(i.e. dealer, hauler) _____

Reason for Acquisition _____

Reason for Disposition _____

E. None of these

Which source listed in # 5 is responsible for the violation?
(Write the letter, A - E) _____

**6. IS THE SLAUGHTER CLASS OF (printed from RVIS as on the lab form) REPRESENTATIVE OF THIS PRODUCER'S PRIMARY BUSINESS?
(circle one)**

YES (go to question 7) / NO (if NO, circle one below)

The general description of this production unit is (circle one):

- | | | |
|--------------------|------------------------------------|-----------------------|
| A. Dairy Farm | D. Poultry Flock | |
| B. Swine Operation | E. Beef Ranch (other than Feedlot) | |
| C. Feedlot (Beef) | F. Veal Operation | |
| | G. Other (Select one number) | |
| | 1. Sales/Auction Barn | 4. Hobby herd/flock |
| | 2. Buyer/Dealer | 5. Multi-species unit |
| | 3. Slaughter Facility | 6. Other |

7. APPROXIMATE SIZE OF BUSINESS (circle one letter below):

No. of Animals (On the premises at the date of inspection/investigation)

- A. 1 - 20
- B. 21 - 100
- C. 101 - 500
- D. 501 - 2000
- E. Over 2000

Note: For dairies use total animals on contiguous production unit. Do not include calves/replacement animals reared by a contractor at remote locations.

8. GENERAL ANIMAL HUSBANDRY PRACTICES OF BUSINESS (provide an answer for each letter):

- A. One individual or multiple individuals are authorized to treat animals:
 (1) One / (M) Multiple
- B. Utilizes services of veterinarian)..... **YES / NO**
 (If yes, please circle one number below)
1. On as-needed basis (not routine)
 2. For herd health programs only, including pregnancy check
 3. For all veterinary medical needs (herd health and as needed)
 4. As a member of staff
- C. Mixes own feed :..... **YES / NO**
 (If yes, please circle all numbers that apply)
1. Grinder/mixer/mill routinely cleaned/flushed after processing of medicated feeds
 2. Uses sequencing to control unsafe contamination
 3. Conforms to cGMPs for mills
 4. Mixes non-medicated feed only
- D. Buys commercial feed (a complete feed) **YES / NO**
- E. Uses medicated milk replacer **YES / NO**
- F. Feeds, or allows the young to suckle milk from treated dams **YES / NO**
- G. Observes the directions of products used during the dry cow period..... **YES / NO**
- H. Water for animals comes from a private water source (wells, etc.) **YES / NO**
- I. Has system for separating treated and non-treated animals **YES / NO**
- J. Keeps medical records **YES / NO**
- Circle all numbers below that are included in medical recordkeeping:**
- | | |
|--------------------------------|--|
| 1- Animal ID | 5- Route of administration |
| 2- Treatment date | 6- Withdrawal time for meat and milk |
| 3- Drug(s)/medicated feed used | 7- Individual who administered drug |
| 4- Dosage(s) given | 8- If treatment recommended by veterinarian |
| | 9-Date animal can be slaughter and/or milk can be used |
- K. Keeps records on the sale and/or purchase of animals..... **YES / NO**
- L. Keeps records on the inventory and accountability of drugs and medicated feeds..... **YES / NO**

Section 3
THE COMPOUND
(Questions 9-15)

THE FOLLOWING QUESTIONS ARE ABOUT THE DRUG(S) WHOSE USE RESULTED IN THE CURRENT TISSUE RESIDUE VIOLATION: (IF MULTIPLE ANIMALS ARE INVOLVED AND USES/CAUSES/TREATMENTS VARY AMONG ANIMALS PLEASE COMPLETE A SET OF THE FOLLOWING QUESTIONS (questions 9-13) FOR EACH ANIMAL. Also if multiple residues are reported for a single sample complete questions 9-13 for each residue reported)

9. NAME OF DRUG USED ON THE ANIMAL WHICH CAUSED THE RESIDUE of _____
(Obtain from the product label if available) If unknown write **UNKNOWN**

DRUG NAME

Trade/Proprietary name preferred

_____ or NDC#

Is the prescription label present? YES / NO (i.e., Caution: Federal Law restricts this drug to use by or on the order of a licensed veterinarian.)

10. DRUG WAS ADMINISTERED AS FOLLOWS :

DOSE (i.e. # cc=s/ # sites) _____ **ROUTE** _____ **FREQUENCY** _____

(FOR **ROUTE**, WRITE IN LETTER USING LIST BELOW):

- | | | |
|------------------|-------------------------------|-------------------|
| A. Intravenous | D. Intramammary | G. Drinking Water |
| B. Intramuscular | E. Oral Bolus, Liquid, Tablet | H. Milk Replacer |
| C. Subcutaneous | F. Feed | I. Intra-Uterine |
| | | J. Topical |

(FOR **FREQUENCY** WRITE IN LETTER USING LIST BELOW):

- | | | |
|---------------------|---------------------------|-------------------|
| A. Once | D. TID(Three times daily) | G. PRN(As Needed) |
| B. SID(Once a day) | E. QID(Four times daily) | H. Other |
| C. BID(Twice a day) | F. EOD(Every other day) | |

11. REASON THE DRUG WAS ADMINISTERED TO THE ANIMAL/HERD/FLOCK...
(circle one letter below):

A. If used because of illness; specify ailment(s) treated :

B. If used as a preventive measure ***(circle all numbers that apply):***

1. Prior to transportation
2. Prior to addition to an established herd/flock
3. Prior to or during introduction to a farm, ranch, or region with endemic disease
4. To aid animal or flock's adjustment to changes in weather conditions
5. Other:

C. If used as a growth promotant/production aid.

D. Other: _____

**12. IS DRUG LABELED FOR THE USE INDICATED IN QUESTION 11:
YES / NO/ CANNOT BE DETERMINED**

A. Product was purchased from? Indicate name, address, and firm type:

Name: _____

Address: _____

(circle one number below)

- | | | |
|-------------------------------------|-------------------------------|----|
| 1. Feed/Supply Store | 4. Mobile Peddler/Salesperson | 2. |
| Mail Order | 5. Veterinarian | |
| 3. Feed From A Commercial Feed Mill | 6. Other:_____ | |

B. Did a veterinarian, through a valid veterinarian-client-patient relationship (VCPR), prescribe the use of the drug in #9?.....**YES / NO**

(If yes, verify and answer 12C and 12D)

Is there a veterinarian's label on the product?.....**YES / NO**

Does the veterinarian's label on the product specify the following:

- | | | |
|-----------------------------------|-----------------|---------|
| 1. Indications for Use?..... | YES / NO | 2. |
| Dosage?..... | YES / NO | 3. |
| Duration of Therapy?..... | YES / NO | 4. |
| Expiration Date?..... | YES / NO | 5. Name |
| and address of practitioner?..... | YES / NO | |
| 6. Contraindications?..... | YES / NO | |
| 7. Route of Administration?..... | YES / NO | |
| 8. Withdrawal Period?..... | YES / NO | |
| 9. Active Ingredients..... | YES / NO | |

COMPLETE BELOW IF A FOLLOW-UP AT THE VETERINARIAN'S IS CONDUCTED (CP 7371.006, Part III, pp. 4-5)

C. Do the veterinarian's records substantiate a valid VCPR?
.....**YES/NO/CANNOT BE DETERMINED**

D. Was the prescribed use;

- 1. Consistent with an approved product's label?.....**YES/NO**
- 2. Modification of indications, dose, or precautions of an approved product?.....**YES/NO**
- 3. Compounded from one or more (approved/unapproved) ingredients?.....**YES/NO**

If #3 is yes, circle one answer for each letter below:

- a. For a **(T) therapeutic** or **(P) production** use?.....**T / P**
- b. Based on **(C) clinical needs** or **(A) anticipation of sale**?.....**C / A**
- c. Product **(I) is** or **(N) is not** promoted for sale?.....**I / N**

If compounded by a veterinarian, list all the components of the product:

Product 1.
 Name _____:
 Components:

Product 2.
 Name _____:
 Components:

Prescribed withdrawal time _____ days

Prescribed withdrawal time _____ days

13. WHAT WAS THE PRIMARY FACTOR CAUSING THIS VIOLATION ?
(circle one letter below):

A. Production Management causes

(If production management is the cause, circle ONE number below:)

1. Animal(s) fed colostrum or milk containing drug residue
2. Animal(s) fed medicated feed by mistake
3. Drug administered to animal(s) by mistake
4. Failure to keep proper animal identity and treatment records
5. Inadequate segregation of treated animal(s)
6. Failure to follow labeled withdrawal time
7. Feed manufacturing cGMP deviations

B. Extra-Label Use

(If extra-label use is the cause, circle ONE below)

1. Veterinarian's prescribed withdrawal period not observed
2. Withdrawal period verbally recommended by veterinarian not observed
3. Animal treated with higher than the recommended/labeled dosage of drug
4. Labelled route of administration not observed
5. No withdrawal period prescribed
6. Drug not approved for species
7. Frequency of treatment different than on label
8. Duration of treatment longer than on label

C. Unable to Determine

D. Interviewee stated drug used was not the same as residue reported by FSIS.

E. Interviewee told purchaser/hauler animal was medicated -animal later diverted for human food.

F. All label/ prescription directions followed and documented, residue still occurred.

G. Other

14. WHAT ARE **ADDITIONAL** FACTORS CONTRIBUTING TO THIS VIOLATION ?
(Circle all letters and numbers that apply below):

A. Production Management causes

1. Animal(s) fed colostrum or milk containing drug residue
2. Animal(s) fed medicated feed by mistake
3. Drug administered to animal(s) by mistake
4. Failure to keep proper animal identity and treatment records
5. Inadequate segregation of treated animal(s)
6. Failure to follow labeled withdrawal time
7. Feed manufacturing cGMP deviations

B. Extra-Label Use

1. Veterinarian's prescribed withdrawal period not observed
2. Withdrawal period verbally recommended by veterinarian not observed
3. Animal treated with higher than the recommended/labeled dosage of drug
4. Labelled route of administration not observed
5. No withdrawal period prescribed
6. Drug not approved for species
7. Frequency of treatment different than on label
8. Duration of treatment longer than on label

C. Unable to Determine

D. Interviewee stated drug used was not the same as residue reported by FSIS.

E. Interviewee told purchaser/hauler animal was medicated - animal later diverted for human food.

F. All label/prescription directions followed and documented, residue still occurred.

G. Other

15. ACTION(S) TAKEN TO EDUCATE INDIVIDUAL/ORGANIZATION(S) RESPONSIBLE FOR CURRENT VIOLATION ON HOW TO PREVENT THE OCCURRENCE OF TISSUE RESIDUE VIOLATIONS IN THE FUTURE (**circle all that apply**):

- A. Discussed the need to adhere to drug-label instructions with special emphasis on dosage, withdrawal time, route of administration, and approved species
- B. Discussed the need to properly identify animals
- C. Discussed the need to keep good medical and sale/purchase records on treated animals
- D. Discussed the need to maintain a cull pen for treated/sick animals, especially the need to separate treated dams (or their products) from sucklings
- E. Discussed availability of husbandry information and consultation services provided by Federal/State/County Extension Services
- F. Discussed inventory and accountability of all drugs and medicated feeds
- G. Other: _____
i.e. Consult vets, QA programs, Training of persons involved w/ drugs, control of access to drugs

ATTACHMENT D – USDA CONTACTS

FSIS Technical Service Center (TSC) The TSC serves as the Agency's center for technical assistance, advice and guidance. Telephone (402) 221-7400 FAX (402) 221-7438

FSIS District Offices**Alameda, CA****District 05****State: California**

Dr. Neal Westgerdes, District Manager
620 Central Avenue
Building 2c
Alameda, CA 94501
Phone: (510)337-5000
Ext. 1 for DM or DDM
FAX: (510)337-5081
Emergency 24-Hour: 1-866-729-9307

Albany, NY**District 65****States: Connecticut, Maine, Massachusetts, New Hampshire, New York, Rhode Island, Vermont**

Mr. Louis Leny, district Manager
230 Washington Ave. Extension
Albany, NY 12203-5369
Phone: (518)452-6870
FAX: (518)452-6870
Emergency 24-Hour: 518-452-6870, Ext. 250

Atlanta, GA**District 85****States: Florida, Georgia, Puerto Rico, Virgin Islands**

Dr. Larry Smith, District Manager
100 Alabama St., SW; Bldg 1924
Suite 3R90
Atlanta, GA 30303
Phone: (404) 562-5900
FAX: (404) 562-5877
Emergency 24-Hour: 1-800-282-7005

Beltsville, MD**District 75****States: Delaware, District of Columbia, Maryland, Virginia, West Virginia**

Dr. Mohamed Ibraheim, District Manager
5601 Sunnyside Ave.
Suite 1-2288 B
Beltsville, MD 20705-5200
Phone: (301) 504-2136
FAX: (301) 504-2140
Emergency 24-Hour: 1-800-289-4116

Boulder, CO**District 15****States: Alaska, American Samoa, Arizona, Colorado, Guam, Hawaii, Idaho, New Mexico, Nevada, Northern Mariana Islands, Oregon, Utah, Washington****Boulder Office**

Dr. Ronald K. Jones, District Manager
Boulder Office
665 South Broadway
Suite B
Boulder, CO 80303
Phone: (303) 497-5411
FAX: (303) 497-7306
24-Hour Emergency: (303) 497-5411

Salem Office

530 Center Street, NE
Mezzanine
Salem, Oregon 97301
Phone: (503) 399-5831
FAX: (503) 399-5636
24-Hour Emergency: (303) 497-5411

Chicago, IL**District 50****States: Illinois, Indiana, Ohio**

Mr. Richard Mackey, District Director

Chicago Office

1919 South Highland Avenue
Suite 115C
Lombard, IL 60148
Phone: (630) 620-7474
FAX: (630) 620-7599
24-Hour Emergency: 1-888-874-6503

Pickerington Office

155 East Columbus Street
Pickerington, OH 43147
Phone: (614) 833-1405
FAX: (614) 833-1067
24-Hour Emergency: 1-888-874-6503

Dallas, TX

District 40

State: Texas

Mr. Alfred Almanza, District Manager
1100 Commerce Street
Room 516
Dallas, TX 75242-0598
Phone: (214) 767-9116
FAX: (214) 767-8230
24-Hour Emergency: (214) 767-9116, Ext.
250

Des Moines, IA

District 25

States: Iowa, Nebraska

Mr. Dennis Greening, District Manager
Room 985, Federal Building
210 Walnut Street
Des Moines, IA 50309
Phone: (515) 727-8960
or 1-800-990-9834
FAX: (515) 727-8991
24-Hour Emergency: (515) 710-1829 or
(515) 240-0181

Jackson, MS

District 90

States: Alabama, Mississippi, Tennessee

Dr. Paul Resweber, District Manager
715 S. Pear Orchard Road, Suite 101
Ridgeland, MS 39157
Phone: (601) 965-4312
FAX: (601) 965-5901
24-Hour Emergency: (601) 662-3407

Lawrence, KS

District 30

States: Kansas, Missouri

Dr. William M. Walker, District Manager
4920 Bob Billings Parkway
Lawrence, KS 66049-3855
Phone: (785) 841-5600
FAX: (785) 841-5623
24-Hour Emergency: (785) 840-0020

Madison, WI

District 45

States: Michigan, Wisconsin

Dr. Linda Madson, District Manager
2810 Crossroads Dr.
Suite 3500
Madison, WI 53718-7969
Phone: (608) 240-4080
FAX: (608) 240-4092
24-Hour Emergency: 1-888-724-3212 Pin
#300267

Minneapolis, MN

District 20

**States: Minnesota, Montana, North
Dakota, South Dakota, Wyoming**

Dr. Nathaniel Clark, District Manager
Butler Square West, Suite 989-C
100 N. 6th Street
Minneapolis, MN 55403
Phone: (612) 370-2400
FAX: (612) 370-2411
24-Hour Emergency: 1-800-923-9535

Philadelphia, PA

District 60

States: New Jersey, Pennsylvania

Mr. Jan T. Behney, District Manager
Mellon Independence Center
701 Market Street – Suite 4100-A
Philadelphia, PA 19106-1576
Phone: (215) 597-4219, Ext. 101
or 1-800-637-6681
FAX: (215) 597-4217
24-Hour Emergency: 1-800-637-6681, Ext.
101 or Ext. 113

Raleigh, NC
District 80
States: Kentucky, North Carolina, South Carolina
Dr. Lewis Burgman, District Manager
6020 Six Forks Road
Raleigh, NC 27609
Phone: (919) 844-8400
or 1-800-662-7608
FAX: (919) 844-8411
24-Hour Emergency: (919) 844-8400

Springdale, AR
District 35
States: Arkansas, Louisiana, Oklahoma
Dr. Marcia Endersby, District Manager
Country Club Center
Bldg. B, Suite 201
4700 South Thompson
Springdale, AR 72764
Phone: (479) 751-8412
FAX: (479) 751-9049
24-Hour Emergency: (479) 751-8412

**Office of Program Planning, Evaluation, and Enforcement
Regional Offices**

Western Region

States: Alaska, American Samoa, Arizona, California, Colorado, Guam, Hawaii, Idaho, Mariana Islands, Nevada, New Mexico, Oregon, Utah, Washington

Regional Manager
620 Central Avenue, Building 2B
Alameda, CA 94501
Phone: (510) 337-5000, Ext. 249
FAX: (510) 337-5080
Emergency: (202) 276-1610

Southwest Region

States: Arkansas, Louisiana, Oklahoma, Texas

Regional Manager
1100 Commerce Street, Room 516
Dallas, TX 75242
Phone: (214) 767-9116, Ext. 400
FAX: (214) 767-8230
Emergency: (214) 763-1853

Great Plains Region

States: Iowa, Kansas, Minnesota, Missouri, Montana, Nebraska, North Dakota, South Dakota, Wyoming

Regional Manager
4920 West 15th Street, Suite B
Lawrence, KS 66049
Phone: (785) 840-9026
FAX: (785) 843-0548
Emergency: (785) 423-5402

Midwest Region

States: Illinois, Indiana, Ohio, Michigan, Wisconsin

Regional Manager
1919 South Highland Avenue, Suite 120C
Lombard, IL 60148
Phone: (630) 916-6226, Ext. 264
FAX: (630) 620-7876
Emergency: (630) 768-8418 (Alert 1)

Southeast Region

States: Alabama, Delaware, District of Columbia, Florida, Georgia, Kentucky, Maryland, Mississippi, North Carolina, Puerto Rico, South Carolina, Tennessee, Virginia, Virgin Islands, West Virginia

Regional Manager
100 Alabama Street SW
1924 Building, Suite 3R90
Atlanta, GA 30303
Phone: (404) 562-5962
FAX: (404) 562-5935
Emergency: (404) 569-3060

APHIS Veterinary Services Offices
(Call Veterinary Services Office to contact current Animal ID Coordinator)

Alabama

Dr. O. W. Hester
USDA, APHIS, VS
P.O. Box 70429
Montgomery, AL 36107
(334) 223-7141
Fax (334) 223-7352
Owen.Hester@usda.gov

Alaska

Dr. Gary L. Brickler
USDA, APHIS, VS
2604 12th Court, SW, Suite B
Olympia, WA 98502
(360) 753-9430
Fax (360) 753-9585
Gary.L.Brickler@usda.gov

Arizona

Dr. Hortentia Harris
USDA, APHIS, VS
1400 E. Southern Ave., Suite 245
Tempe, AZ 85282
(480) 491-1002
Fax (480) 491-1895
Hortentia.D.Harris@usda.gov

Arkansas

Dr. Ronnie Blair
USDA, APHIS, VS
1200 Cherry Brook Dr., Suite 300
Little Rock, AR 72211
(501) 224-9515
Fax (501) 225-5823
Ronnie.E.Blair@usda.gov

California

Dr. Paul Ugstad
USDA, APHIS, VS
9580 Micron Ave., Suite E
Sacramento, CA 95827
(916) 857-6170
Fax (916) 857-6196
Paul.O.Ugstad@usda.gov

Colorado

Dr. Jerry W. Diemer
USDA, APHIS, VS
755 Parfet Street, Suite 136
Lakewood, CO 80215
(303) 231-5385
Fax (303) 231-5390
Jerry.W.Diemer@usda.gov

Florida

Dr. Robert E. Southall
USDA, APHIS, VS
7022 NW 10th Place
Gainesville, FL 32605-3147
(352) 333-3120
Fax (352) 333-6849
Robert.E.Southall@usda.gov

Georgia

Dr. Edgardo Arza
USDA, APHIS, VS
1498 Klondike Rd., Suite 200
Conyers, GA 30094
(770) 922-7860
Fax (770) 483-9000
Edgardo.Arza@usda.gov

Hawaii

Dr. Gary L. Brickler
USDA, APHIS, VS
2604 12th Court, SW., Suite B
Olympia, WA 98502
(360) 753-9430
Fax (360) 753-9585
Gary.L.Brickler@usda.gov

Idaho

Dr. Cynthia Gaborick
USDA, APHIS, VS
9158 West Black Eagle Drive
Boise, ID 83709
(208) 378-5631
Fax (208) 378-5637
Cynthia.M.Gaborick@usda.gov

Illinois

Lennis Knight
 USDA, APHIS, VS
 2815 Old Jacksonville Rd., Suite 104
 Springfield, IL 62704
 (217) 241-6689
 Fax (217) 241-6695
Lennis.C.Knight@usda.gov

Indiana

Dr. Francisco Collazo Mattei
 USDA, APHIS, VS
 5685 Lafayette Road, Suite 400
 Indianapolis, IN 46254-6158
 (317) 290-3300
 Fax (317) 290-3311
Francisco.Collazo-Mattei@usda.gov

Iowa

Dr. Kevin L. Petersburg
 USDA, APHIS, VS
 Federal Bldg., Rm. 891
 210 Walnut Street
 Des Moines, IA 50309
 (515) 284-4140
 Fax (515) 284-4156
Kevin.L.Petersburg@usda.gov

Kansas

Dr. Kevin P. Varner
 USDA, APHIS, VS
 1947 NW Topeka Blvd., Suite F
 Topeka, KS 66608
 (785) 235- 2365
 Fax (785) 235-1464
Kevin.P.Varner@usda.gov

Kentucky

Dr. Roger J. Odenweller
 USDA, APHIS, VS
 P.O. Box 399
 Frankfort, KY 40602
 (502) 227-9651
 Fax (502) 223-7121
Roger.Odenweller@usda.gov

Louisiana

Dr. Joel Goldman
 USDA, APHIS, VS
 5825 Florida Blvd., Rm 1140
 Baton Rouge, LA 70806-9985
 (225) 389-0436
 Fax (225) 389-0524
Joel.Goldman@usda.gov

Maryland (DE, DC)

Dr. David F. Vogt
 USDA, APHIS, VS
 1598 Whitehall Road, Suite A
 Annapolis, MD 21401
 (410) 349-9708
 Fax (301) 261-8113
David.F.Vogt@usda.gov

Massachusetts (CT, ME, NH, RI, VT)

Dr. William G. Smith
 USDA, APHIS, VS
 160 Worcester-Providence Road
 Sutton Square Plaza, Suite 20
 Sutton, MA 01590-9998
 (508) 865-1421, 22
 Fax (508) 865-9317
William.G.Smith@usda.gov

Michigan

Dr. Reed Macarty
 USDA, APHIS, VS
 3001 Coolidge Road, Suite 325
 East Lansing, MI 48823
 (517) 324-5290
 Fax (517) 324-5289
Reed.E.Macarty@usda.gov

Minnesota

Dr. Michael L. Stine
 USDA, APHIS, VS
 251 Starkey Street
 Bolander Bldg., Suite 229
 St. Paul, MN 55107
 (651) 290-3691
 Fax (651) 228-0654
Michael.L.Stine@usda.gov

Mississippi

Dr. Charles P. Nettles
 USDA, APHIS, VS
 345 Keyway Street
 Flowood, MS 39232
 (601) 965-4307
 Fax (601) 965-5535
Charles.Nettles@usda.gov

Missouri

Dr. Robert L. Fischer
 USDA, APHIS, VS
 P.O. Box 104418
 Jefferson City, MO 65110-4418
 (573) 636-3116
 Fax (573) 636-4384

Robert.L.Fischer@usda.gov

Montana

Area Veterinarian-in-Charge - Vacant
USDA, APHIS, VS
208 North Montana Ave., Suite 101
Helena, MT 59601-3837
(406) 449-5407
Fax (406) 449-5439

Nebraska

Dr. Kathleen Akin
USDA, APHIS, VS
P.O. Box 81866
Lincoln, NE 68501
(402) 434-2300
Fax (402) 434-2330
Kathleen.J.Akin@usda.gov

Nevada

Dr. Paul Ugstad
USDA, APHIS, VS
9580 Micron Ave., Suite E
Sacramento, CA 95827
(916) 857-6170
Fax (916) 857-6196
Paul.O.Ugstad@usda.gov

New Jersey

Jonathan Zack
USDA, APHIS, VS
Mercer Corporate Park
320 Corporate Blvd.
Robbinsville, NJ 08691-1598
(609) 259-8387
Fax (609) 259-2477
Jonathan.T.Zack@usda.gov

New Mexico

Dr. Michael T. Greenlee
USDA, APHIS, VS
6200 Jefferson Street, NE, Suite 117
Albuquerque, NM 87109
(505) 761-3160
Fax (505) 761-3176
Michael.T.Greenlee@usda.gov

New York

Roxanne Mullaney
USDA, APHIS, VS
One Winners Circle, Suite 100
Export/Area Office
Albany, NY 12205
(518) 453-0187
Fax (518) 453-0213

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Roxanne.C.Mullaney@usda.gov

North Carolina

Eric Coleman
USDA, APHIS, VS
930 Main Campus Drive, Suite 200
Raleigh, NC 27606
(919) 855-7700
Fax (919) 855-7720
Export Line (919) 855-7701
Eric.S.Coleman@usda.gov

North Dakota

Area Veterinarian-in-Charge - Vacant
USDA, APHIS, VS
3509 Miriam Ave., Suite B
Bismarck, ND 58501
(701) 250-4210
Fax (701) 250-4471

Ohio

Dr. Susan Skorupski
USDA, APHIS, VS
12927 Stonecreek Drive
Pickerington, OH 43147
(614) 469-5602
Fax (614) 866-1086
Susan.Skorupski@usda.gov

Oklahoma

Dr. Brian H. Espe
USDA, APHIS, VS
4020 North Lincoln Blvd., Suite 101
Oklahoma City, OK 73105
(405) 427-9413
Fax (405) 427-9451
Brian.H.Espe@usda.gov

Oregon

Dr. Don Herriot
USDA, APHIS, VS
530 Center St., NE, Suite 335
Salem, OR 97301
(503) 399-5871
Fax (503) 399-5607
Don.E.Herriott@usda.gov

Pennsylvania

Dr. Enzo R. Campagnolo
USDA, APHIS, VS
2301 N. Cameron St., Rm. 412
Harrisburg, PA 17110
(717) 782-3442
Fax (717) 782-4098

Enzo.R.Campagnolo@usda.gov

Puerto Rico

Dr. Miguel A. Borri-Diaz
USDA, APHIS, VS
IBM Building
654 Munoz Rivera Avenue, Suite 700
Hato Rey, PR 00918
(787) 766-6050
Fax (787) 766-5159
Miguel.A.Borri-Diaz@usda.gov

South Carolina

Dr. Delorias Lenard
USDA, APHIS, VS
9600 Two Notch Road, Suite 10
Columbia, SC 29229
(803) 788-1919
Fax (803) 788-2102
Delorias.M.Lenard@usda.gov

South Dakota

Dr. Lynn. A. Tesar
USDA, APHIS, VS
314 S. Henry, Suite 100
Pierre, SD 57501-0640
(605) 224-6186
Fax (605) 224-8451
Lynn.A.Tesar@usda.gov

Tennessee

Dr. Mark Davidson
USDA, APHIS, VS
P.O. Box 110950
Nashville, TN 37222
(615) 781-5310
Fax (615) 781-5309
Mark.L.Davidson@usda.gov

Texas

Area Veterinarian-in-Charge - Vacant
USDA, APHIS, VS
Thornberry Bldg., Rm. 220
903 San Jacinto Blvd.
Austin, TX 78701
(512) 916-5551
Fax (512) 916-5197

Utah

Dr. Robert A. DeCarolis
USDA, APHIS, VS
176 N. 2200 West, Suite 230
Airport Park, Bldg. #4
Salt Lake City, UT 84116

(801) 524-5010
Fax (801) 524-6898
Robert.A.DeCarolis@usda.gov

Virginia

Dr. Terry L. Taylor
USDA, APHIS, VS
Washington Bldg., 6th Floor
1100 Bank Street
Richmond, VA 23219
(804) 771-2774
Fax (804) 771-2030
Terry.L.Taylor@usda.gov

Washington

Dr. Gary L. Brickler
USDA, APHIS, VS
2604 12th Court, SW., Suite B
Olympia, WA 98502
(360) 753-9430
Fax (360) 753-9585
Gary.L.Brickler@usda.gov

West Virginia

Dr. Susan Skorupski
USDA, APHIS, VS
12927 Stonecreek Drive
Pickerington, OH 43147
(614) 469-5602
Fax (614) 866-1086
Susan.Skorupski@usda.gov

Wisconsin

Dr. Linn Wilbur
USDA, APHIS, VS
6510 Schroeder Road, Suite 2
Madison, WI 53711
(608) 270-4000
Fax (608) 270-4001
Linn.A.Wilbur@usda.gov

Wyoming

Dr. Bret A. Combs
USDA, APHIS, VS
5353 Yellowstone Road, Room 209
Cheyenne, WY 82009
(307) 772-2186
Fax (307) 772-2592
Bret.A.Combs@usda.gov

GIPSA

Headquarters

GIPSA
1400 Independence Ave., SW
Room 1641
South Bldg
Washington, DC 20250
(202) 720-7051

Regional Offices

P&SP
75 Spring Street
Suite 230
Atlanta, GA 30303
(404) 562-5840

P&SP
1 Gateway Centre
3950 Lewiston
Suite 200
Aurora, CO 80011
(303) 375-4240

PS&P
Federal Bldg
Room 317
210 Walnut Street
Des Moines, IA 50309
(515) 323-2590

States Covered

AL, AK, CT, DC, DE, FL, GA, LA, MA, MD, ME,
MS, NC, NH, NJ, NY, PA, RI, SC, TN, VA, VT,
WV

AK, AZ, CA, CO, HI, ID, KS, MT, NE, NM, OK,
OR, TX, VT, WA, WY

IA, IL, IN, KY, OH, MI, MO, MN, ND, SD, WI

ATTACHMENT E – GIPSA / TITLE 18 MEMO

DEPARTMENT OF HEALTH & HUMAN SERVICES

Date JUN 23 1987

From Acting Associate Director for
Surveillance and Compliance, HFV-200

Subject 403(a), Packers and Stockyards Act, and Title 18,
Chapter 100 References in Regulatory Letters: Illegal Residues

All District offices

We have recently had occasion to review a number of issues regarding Regulatory Letters issued on illegal tissue residue violations in cases where false certificates were identified under the *USDA* Voluntary Veal Certification Program.

Our considerations in this memorandum are based on the presumption that you have other supportable Title 21 charges to include in your Regulatory Letter. We are not prepared to issue Regulatory Letters addressing Title 18 alone. In addition, *FDA* is not committing itself to take regulatory action under Title 18, or the PSA Act for false drug residue certificates, which are in fact, presented to another Federal agency, i.e. FSIS, as it would be their prerogative and responsibility to bring such action our intent in addressing Title 18, in these circumstances, is to inform the violator that another agency (PSA or FSIS) may be interested in taking action under their Acts (7 U.S.C. 181 et. seq, 15 U.S.C. 50) or under 18 U.S.C. 1001, for false information presented to that agency. This is the result of an agreement with those agencies that we will convey the message concerning Title 18 violations in letters we issue.

1. Title 18 (18 U.S.C. 1001)

(a) When an illegal tissue residue violation occurs and the offering of a false certificate is well documented, demonstrating a willful, intentional act, we recommend the District consider referral of the case to the Packers and Stockyards Administration (PSA) and the Food Safety Inspection Service (FSIS) (see attached lists for referral), since a felony prosecution may be appropriate. A Title 18 reference in a Regulatory Letter would not be appropriate in these circumstances.

(b) When evidence of false certificates exists, without a well documented, willful, intentional act, we recommend the following cautionary statement:

We caution you that it is a violation of United States Code, Title 18, Section 1001 (18 U.S.C. 1001) (copy enclosed) to make intentional or willful, false, fictitious or fraudulent statements or representations in any matter within the jurisdiction of any department or

agency of the United States, and that you may be subject to severe penalties under the criminal provisions of 18 U.S.C. 1001.

2. Likewise in all cases where evidence of false certificates exist, with documentation of an intentional act, *the* District should refer, in the information portion of the Regulatory Letter, to possible action by the Packers and Stockyards Administration, under the Packers and Stockyards Act (7 U.S.C. 181 et. seq. and 15 U.S.C. 50), in addition to referral of the case to the Packers and Stockyards Administration.

Example: We note that you have provided (a) false drug residue certificate(s) on the calf (calves) identified with Back Tag ____, which may subject you to possible action under the Packers mid Stockyards Act (7) U.S.C. 181 et. seq. and 15 U.S.C. 50 by the Packers and Stockyards Administration.

3. In addition, a copy of the Regulatory Letter should be sent to the local/regional office of the Packers and Stockyards Administration, in all cases where false certificates exist. A copy should also be sent to the local compliance office of the Food Safety and Inspection Service. (Use attached lists for mailing copies)

4. 403(a) Charge

A 403(a) charge has been proposed in at least one tissue residue case, for the offering of a false drug residue certificate, considering the certificate as labeling, and the "labeling" as false and misleading.

We currently are unable to support a 403(a) misbranding charge for the offering of a false certificate by the seller of an animal. We do not believe a 403(a) charge is appropriate in such circumstances.

**ATTACHMENT F-2
Example of Slaughter Plant Inspector Affidavit**

AFFIDAVIT

Sample No. _____

STATE OF _____

COUNTY OF _____

Before me, _____, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803: Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. I of 1953, Secs.1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509. 93 Statutes at Large 965 (20 U.S.C. 3508), effective May 4, 1980; to administer or take oaths. Affirmations and affidavits, personally appeared _____ in the county and State aforesaid, who, being duly sworn, deposes and says:

On September ____, 200__, a F.A.S.T. test that I ran yielded a positive result.

Whenever a tissue sample is collected for laboratory analysis an FSIS Form 10, Q-02-2 is prepared by filling in items one (1) through seventeen (17). The tissue and the forms are then sent directly to the USDA laboratory in _____ for identification and quantification of the drug residue. The samples are packed in specially constructed shipping ice boxes which contain bottles of frozen water to refrigerate the samples which are shipped by overnight delivery. I or my staff collected the sample and performed the F.A.S.T. screening test on the following animal:

Sample Form No. _____
Collection Location _____
Collection Date _____
Retain Tag Number _____
Animal ID Tag(s) _____

AFFIANT'S SIGNATURE AND TITLE

FIRMS NAME AND ADDRESS (Include ZIP Code)

Subscribed and sworn to before me at _____ (City /State) this day of _____

(Employee's Signature)

Employee of the Department of Health and Human Services designated under Act of January 31, 1925. Reorganization Plan IV effective June 30, 1940. Reorganization Plan No, I of 1953, effective April 11, 1953; and PL 96-88 effective May 4, 1980.

**ATTACHMENT G
DRUG INVENTORY****TISSUE RESIDUE INSPECTIONS**

Drug inventory to be completed by all Federal and State investigators conducting tissue residue inspections.

FSIS Sample Number: _____

Fiscal Year: _____

State: _____

FDA District: _____

Type of Animal: _____

Please circle the drug tradename of **all** drugs found at the firm (drugs are listed alphabetically by active ingredient, and under each active ingredient by dosage form and trade name.) The information collected via this inventory will be used to develop future sampling strategies. While completing this document please look for and document the use of any illegally compounded products, Animal Medicinal Drug Use Clarification Act (AMDUCA)-prohibited drugs, or unapproved drugs (a further description of these products can be found at the end of this inventory). Space has been allotted at the end of the list for additional drugs you may find on the premises. Return this drug inventory survey to your local FDA district Tissue Residue Coordinator. If you have any questions on this inventory please contact Deborah Cera at (301)827-0181.

Acepromazine Maleate (tranquilizer)

- Injection
 - PromAce® Injectable
 - Acepromazine Maleate Injection

- Oral
 - PromAce® Tablets
 - Acepromazine Maleate Tablets

Albendazole: (antiparasitic, benzimidazole family)

- Oral: Valbazen®

Albuterol: (bronchodilator, Beta-agonist) Approved for use in horses only. Not approved in cattle or swine.

- Intranasal: Torpex™

Amikacin (antimicrobial, aminoglycoside {AGS})

- Injection
Amiglyde-V
Amikacin Sulfate Injection

Amoxicillin Trihydrate (antimicrobial, penicillin family beta lactam)

- Oral:
Amoxi-Doser
Amoxi-Bol
Amoxi-Sol
Amoxi-Tabs
Amoxi-Drop® Oral Suspension
Clavamox® Tablets
Clavamox® Drops
Robamox®-V Tablets
- Injectable
Amoxi-Inject 25 Grams
Amoxi-Inject 3 Grams
Robamox®-V
- Intramammary: Amoxi-Mast

Ampicillin Anhydrous: (antimicrobial, penicillin family beta lactam)

- Injectable: Omnipen 250 mg

Ampicillin Sodium: (antimicrobial, penicillin family beta lactam)

- Injectable: Amp-Equine

Ampicillin Trihydrate (antimicrobial, penicillin family beta lactam)

- Injectable:
 - Polyflex®
 - Princillin Injection
 - Ampicillin Trihydrate
 - Princillin Injection 200 mg
 - Ampi-Ject
- Oral:
 - Princillin Bolus
 - Ampi-Bol
 - Princillin Capsules 125 mg
 - Princillin Capsules 250 mg
 - Princillin Capsules 500 mg
 - Princillin "125" For Oral Suspension
- Water: Princillin Soluble Powder

Amprolium: (anticoccidial)

- Water:
 - Amprovine 9.6% Solution
 - Amprovine 20% Soluble Powder
 - Corid 20% Soluble Powder
- Medicated Feed:
 - Broiler PMX No.1620,
 - Amprol HI-E® Plus
 - Amp Ethopabate CTC® Sodium Sulfate
 - Erythro® (Low Lev) / Amp plus Etho

Swisher Super Broiler 300-108;
Swisher Super Broiler 400-112
Chick Grower-Developer Fortified
Amprol Plus / Lincomix® / Roxarsone
Lincomix® / Amprol Plus
Amprol HI-E® / Roxarsone
Amprol HI-E® / BMD® / Roxarsone
Rainbrook Broiler Premix No.1
Rainbow Broiler Base Concentrate
Rainbow Broiler Base Concentrate
Amprol HI-E® & Bambermycins
Amprol HI-E® / Flavomycin®
3-Nitro® / Amprol HI-E® / Flavomycin®
3-Nitro® / Amprol / Flavomycin
3-Nitro® / Amprol / Flavomycin®
Zinc Bacitracin & Amprol HI-E®
Baciferm® / Amprol HI-E® Premix
Amprol / Carb-O-Sep®
Amprol HI-E® / Stafac®
Flavomycin® / Amprolium
3-Nitro® / Amprol® / BMD®
Amprol® / BMD®
Albac® / Amprol Hi-E®
3-Nitro® / Albac® / Amprol Hi-E®
3-Nitro® / Albac® / Amprol Hi-E®

- Oral: Purina® Liquid Amprol

Aspirin: (Non Steroidal Anti Inflammatory {NSAID})

- Oral: boluses

Boldenone Undecylenate (anabolic steroid) Controlled Drug (DEA)

- Injectable: Equipoise®

Bovine Somatotropin (growth hormone)

- Injectable: Sometribove Zinc)Posilac 1 Step®

Butorphanol (analgesic, opioid) Controlled Drug (DEA)

- Injectable:
 - Torbutrol® Injection
 - Torbugesic®
 - Torbugesic-SA ®
 - Dolorex®
- Oral: Torbutrol® Tablets

Carbadox (anticoccidial)

- Medicated Feed:
 - Mecadox® Premix 10
 - Banminth® / Mecadox®

Ceftiofur: (antimicrobial, cephalosporin family beta lactam)

- Injectables:
 - Excenel®
 - Naxcel®

Cephapirin (antimicrobial, cephalosporin family beta lactam)

- Intramammary:
 - Cefa-Dry®
 - Tomorrow® Infusion
 - Cefa-Lak®
 - Today® Intramammary Infusion

Chloramphenicol (antimicrobial) Extra label use prohibited in Food Animals
(chloramphenicol drugs below are small animal approvals)

- Injection: Mychel-Vet Injection

- Oral:
 - Chlorasol
 - Chloromycetin Tablets 100 mg
 - Chloromycetin Tablets 250 mg
 - Chloromycetin Tablets 500 mg
 - Chlora-Tabs 100
 - Tevcocin Tablets
 - Amphicol-V
 - Chloromycetin Ophthalmic Ointment
 - Chloramphenicol Capsules
 - Chloricol
 - Mychel-Vet Capsules (50 mg)
 - Chloramphenicol Capsules
 - Anacetin Tablets
 - Mychel-Vet Tabs
 - Medichol Tablets

- Topical chloramphenicol:
 - Chlorasone Ophthalmic Ointment
 - Chloramphenicol 1% Ophthalmic
 - Vetrocloricin Ophthalmic Ointment

Chlortetracycline: (antimicrobial, tetracycline family)

- Medicated feed
 - Aureomix S 700-A
 - Aureomix S 700-E
 - Aureomix S 700 Crumbles
 - Aureomix S 700 g
 - Chlorachel™ 10
 - Chlorachel™ 20
 - Chlorachel™ 35
 - ChlorMax™ 10 Type A Medicated Article
 - CLTC-10
 - CLTC-20
 - CLTC-30
 - CLTC-50
 - CLTC-50 MR
 - Pennchlor™ 64
- Milk replacer: Pfichlor 100S Milk Replacer Type A Medicated Article
- Oral
 - Aureomycin® Tablets 25 mg
 - Calf Scour Boluses,
- Water
 - Soluble powder
 - Aureomycin® Soluble Powder

Chlorothiazide: (diuretic)

- Oral: Diuril® bolus

Clenbuterol: (beta agonist) Extra label use prohibited in food animals

- Oral : Ventipulmin®

Clindamycin (antimicrobial, lincosamide family)

- Oral:
Antirobe® Capsules,
Antirobe® Aquadrops Liquid
Clindamycin Hydrochloride Oral Liquid
Clinsol®
Clindamycin Hydrochloride Capsules
Clintabs®

Cloxacillin (antimicrobial, penicillin family beta lactam)

- Intramammary
Boviclox
Dry-Clox®
Dry-Clox® Intramammary Infusion
Orbenin DC, Dariclox®

Danofloxacin (antimicrobial, fluoroquinolone family) Extra label use prohibited in food animals

- Injection: A180® (beef cattle)

Dihydrostreptomycin (antimicrobial, aminoglycoside family)

- Intramammary:
Quartermaster® Dry Cow Treatment
Dry-Mast
- Injection:
Dihydrostreptomycin
Pfizer-Strep
- Bulk drug¹:
Dihydrostreptomycin Sulfate

¹ Bulks drugs prohibited from use in compounded drugs for Animals, under AMDUCA!
DATE OF ISSUANCE: August 1, 2005
MINOR CORRECTIONS: August 23, 2005
FORM FDA 2438

Dexamethazone: (anti-inflammatory long acting glucocorticoid [steroid])

- Injectable
 - Azium® Aqueous Suspension Veterinary
 - Voren® Suspension, generics
- Oral
 - Azium® Boluses
 - Azium® Powder 10 mg
 - Naquasone® Bolus,

Decoquinat (anticooidal, quinolone)

- Medicated feed:
 - Deccox® Type A Medicated Article
 - Deccox® / Lincomycin
 - Decoquinat & Lincomycin
 - 3-Nitro® / Deccox®
 - Albac® / Deccox®; Broiler Finisher Medicated
 - ChlorMax™ / Deccox®
 - Decoquinat & Chlortetracycline
 - Lincomix® / Deccox®
 - Deccox® / Lincomycin
 - Decoquinat & Lincomycin
 - 3-Nitro® / Deccox® / Albac®
 - Deccox® - M Medicated Powder for Whole Milk
 - 3-Nitro® / BMD® / Deccox®
 - BMD® / Deccox®
 - Chloromax® / Deccox®
 - Decox® / Rumensin®
 - Deccox® / Rumensin® / Tylan®
 - Aureomycin® / Deccox®
 - 3-Nitro® / Albac® / Deccox®
 - Albac® / Deccox®

Detomidine (sedative, nonopioid)

- Injectable: Dormosedan™

Dimethyl sulfoxide (DMSO): (NSAID, solvent)

- Topical: Domoso® Solution, Domoso® Gel

Dinoprost Tromethamine: (hormone, synthetic prostaglandin analog)

- Injectable: Lutalyse® Sterile Solution

Dipyrrone: (NSAID) Not approved in the US!

- injectable

Enrofloxacin: (antimicrobial-fluoroquinolone family) Extra label use prohibited in food animals

- Injection: Baytril® 100 Injectable Solution (beef cattle), Baytril® Antibacterial Injectable Solution (dogs)
- Oral: Baytril® Antibacterial Tablets (dogs); Baytril® Taste Tabs™ Antibacterial Tablets (dogs); Baytril® 3.23% Concentrate Antimicrobial Solution (chickens)
- Topical: Baytril® Otic (dogs)

Eprinomectin (antiparasitic-ivermectin family)

- Topical Pour-On
Ivomec® Eprinex™ Pour-On for Beef and Dairy Cattle
Ivomec® Eprinex™ Pour-On for Cattle

Erythromycin (antimicrobial-macrolide family)

- Injectable: Erythro® - 100, 200; Gallimycin® Injectable, Erythro®-100 Injection
- Intramammary: Erythro®-36 Dry; Gallimycin®-36 Dry, Erythromast 36, Gallimycin®-36 Sterile
- Medicated feed: Gallimycin® 50

Estradiol (hormone, nonsynthetic)

DATE OF ISSUANCE: August 1, 2005
MINOR CORRECTIONS: August 23, 2005
FORM FDA 2438

- Implants:
Compudose 200
Compudose 400
Revalor[®]-200
Revalor[®]-H
Revalor[®]-IH
Synovex[®] Plus

Estradiol Benzoate (hormone, synthetic)

- Implant:
Component[®] TE-G with Tylan[®]
Component[®] TE-S with Tylan[®]
Synovex[®]-C
Synovex[®]-S
Synovex[®]-H

Estradiol Cypionate (hormone, synthetic) Not approved in US

- Injection: Estradiol Cypionate

Fenbendazole: (antiparasitic, benzimidazole family)

- Oral:
 - Panacur® Suspension 10% (Rx label)
 - Panacur® Granules 22.2%
 - Panacure®-C, Panacur® Paste
 - Safeguard® (OTC label) –paste
 - Safe-Guard® Suspension 10%
 - Purina® Worm-A-Rest Litter Pack
- Medicated feed:
 - Safeguard® Type A medicated article
 - BMD® / Safe-Guard®
- Medicated feedblocks: Safe-Guard® Enproal Feedblocks

Florfenicol (antimicrobial, chloramphenicol family)

- Injection: Nuflor® Injection
- Oral: Nuflor® Concentrate Solution

Flunixin meglumine: (NSAID)

- Injection:
 - Banamine® injectable Solution
 - Flunixin Meglumine Injection
 - Flunixin Meglumine Solution
- Oral:
 - Banamine® paste
 - Banamine granules

Furazolidone [see nitrofurazone]: (antimicrobial-nitrofurans family) Extra label use prohibited in food animals

- Topical:
 - Furox® Aerosol Powder
 - Topazone Aerosol Powder

Furosemide: (diuretic)

- Injection: Lasix®

Gentamicin: (antimicrobial, aminoglycoside)

- Dip (turkey eggs):
 - Garasol® Solution
 - Gentasol
- Injectables: ***No approvals in Cattle, very long preslaughter withdrawal***
 - Gentocin®
 - Garasin®
 - Garasol®
 - Gentamicin Sulfate Inj. Sol.
 - Gentamicin Sulfate Solution
 - Legacy Sterile Solution
 - Gentaglyde™ Solution
 - Gentamex™ 100
 - Gentamicin Sulfate Solution
- Intramammary: *none approved* (may dilute in saline, or reconstitute)
- Ophthalmic:
 - Gentocin® Durafilm Ophthalmic Solution
 - Gentocin® Ophthalmic Ointment
 - Gentocin® Pink Eye Spray
- Oral:
 - Garacin Oral Solution
 - Gentocin® Oral Solution
 - Gentocin® (Garacin) Pig Pump Oral Solution
 - Gentocin® (Garacin) Soluble Powder
 - Gentamicin Sulfate Pig Pump Oral Solution
 - Gentoral®

- Topical:
 - Gentocin® Otic Solution
 - Topagen® Ointment
 - Gentocin® Topical Spray
 - Otomax®
 - Mometamax™ Otic Suspension
 - Betagen™ Topical Spray
 - Tri-Otic Ointment
 - Gentavet® Otic Solution
- Water: Gen-Gard™ Soluble Powder

Hetacillin (antimicrobial, penicillin family beta lactam)

- Intramammary:
 - Hetacin® K
 - Hetacin® K Intramammary Infusion

Isoflupredone: (anti-inflammatory, glucocorticoid)

- Injectable: Predef® 2x Sterile Aqueous Suspension
- Topical: Neo Predef® Sterile Ointment

Ivermectin: (antiparasitic, ivermectin family)

- Injection:
 - Eqvalan® Injection
 - Ivomec® F Injection For Cattle
 - Ivomec® Plus Injection For Cattle
 - Ivomec® .27% Injection Grower And Feeder Pigs
 - Ivomec® 1% Injection
 - Ivomec® 1% Injection Cattle And Swine
 - Ivomec® Injection
- Oral:
 - Eqvalan® Oral Liquid For Horses

Eqvalan® Oral Liquid

Ivomec® Liquid

Eqvalan®; Eqvalan® Paste For Horses

Ivomec® Cattle Paste 0.153%

Ivomec® Sustained-Release Bolus for Cattle

Phoенectin™ Injection for Cattle and Swine

Phoенectin™ Paste 1.87%

Iversol Liquid for Horses

Equell™

Primectin™ Equine Oral Liquid

Primectin™ Drench for Sheep

Ivercide™ Liquid for Horses

Ivermectin Liquid for Horses

Phoенectin™ Liquid for Horses

- Topical Pour On:

Ivomec® Pour-On For Cattle

Ivomec® Premix for Swine

Ivomec® Premix for Swine and Lincomix® Premix

BMD® / Ivomec® Premix for Swine

Ivermectin Pour-On for Cattle

Phoенectin™

Phoенectin™ Pour-On for Cattle

Iver-On™

Virbamec™ Pour-On

Privermectin™

Ecomectin

- Medicated Feed: Ivomec® Premix plus BMD®

Kanamycin: (antimicrobial)

- Injectable: Kantrim® 200

- Oral: Amforol® Suspension

Ketamine: (anesthetic) Controlled Drug (DEA). Should not be on the farm unless in the Vet's truck

- Injectable: Ketaset®

Ketoprofen: (NSAID)

- Injectable: Ketofen®

Lasalocid: (anticoccidial-ionophore family)

- Medicated feeds:
Avatec® Premix
Bovatec® Premix
Bovatec® Type A Medicated Article)
Moorman's® Cattle Minerals BT

Levamisol: (antiparasitic, imidiathiazole family)

- Oral:
Ripercol L Bolus
Tramisol® Cattle Wormer Bolus
Ripercol L Soluble Drench Powder
Ripercol L Wormer Oblets
Tramisol® Sheep Wormer Oblets
Levasole® Soluble Drench Powder
Tramisol® Soluble Drench Powder

Lincomycin: (antimicrobial, lincosamide family)

- Injectable:
Lincomix® Injectable – 25
Lincomix® Injectable – 50
Lincomix® Injectable – 100
Lincomix® Injectable – 300
Lincocin® Sterile Solution (Rx)
Lincomycin Injectable 30%

- Topical: Lincocin® Aquadrops
- Oral: Lincocin® Tablets
- Medicated feed:
 - Lincomix® Feed Medication Types A, B
 - Lincomix® / Amprol Plus / Roxarsone
 - Lincomix® & Amprol Plus
 - Lincomix®, Lincomix® / Deccox®
 - Coyden® / Lincomix®
 - Lincomix® / Bonaid
 - Lincomycin & Buquinolate,
 - Deccox® / Lincomycin
 - Decoquate & Lincomycin,
 - Lincomix® / Zoamix®, Coban® / Lincomix®
 - Coban® / Lincomix®
 - Coban® / Lincomix® / Roxarsone, Nicarbazin Lincomycin Premix
 - 3-Nitro® / Avatec® / Lincomycin
 - Banminth® / Lincomix®
 - Purina® Check-R-Ton Li
 - Linco-8
 - Linco-20
 - Cadco Li-8
 - Cadco Li-20
 - Link-8
 - Link-20
 - Swine L-4
 - Swine L-8
 - Swine L-20
 - Linco 8
 - Linco 20
 - Lincomycin 4 Antibiotic Premix

Lincomycin 5 Antibiotic Premix

Lincomycin 10 Antibiotic Premix

Lincomycin 20 Antibiotic Premix

Linco 8

Linco 20

Nutra-Mix Linco 4

Master Mix Linco Option 5

Master Mix Linco Option 10

Micro-Pak LX

Linco 4

Linco 20

Bio-Cox® / Lincomix®

Banminth® / Lincomix®

Banminth® / Lincomix® 20

Lincomix® / Stenorol®

3-Nitro® / Bio-Cox® / Lincomix®

Lincomix® / Maxiban®

Lincomix® Type A Medicated Article/ Safe-Guard® Type A Medicated Article

Ivomec® Premix for Swine and Lincomix® Premix

3-Nitro® / Lincomix® / Sacox®

Sacox® / Lincomix®

3-Nitro® / Lincomix® / Nicarmix 25®

Lincomix® / Nicarmix 25®

- Water:

Lincomix® Soluble Powder

L-S 50 Water Soluble® Powder

Lincomycin Hydrochloride Soluble Powder

Lincomycin Soluble

Linco Soluble

Lincosol Soluble Powder

Melengestrol Acetate (MGA): (hormone, synthetic)

- Medicated Feed Ingredient:
MGA® 100 / Rumensin® / Tylan®
MGA® 200 / Rumensin® / Tylan®, MGA® 100 Premix
MGA® 200 Premix
MGA® 500 Liquid Premix

Metronidazole: (antiprotozoal, nitroimidazole family) Extra label use prohibited in food animals

- Oral: Flagyl® (human approval only, no animal approval)

Monensin: (anticoccidial-ionophore family)

- Medicated Feed:
Rumensin®
Rumensin® 80
Coban® - 45
Coban® - 60
Coban® - 110
Elancoban-100

Neomycin sulfate: (antimicrobial, aminoglycoside family)

- Oral:
Biosol® Sterile Solution
Biosol® Sterile Solution 50 mg
Neo-Sol 50®
NEORAL Oral Solution
- Water:
Neomix® 325 Soluble Powder
Neomix® AG 325 Soluble Powder
Neomycin 325 Soluble Powder

Nitrofurazone: (antimicrobial, nitrofurazone family) Extra label use prohibited in food animals

- Topical:
 - Furacin®
 - NFZ® Puffer
 - Nitrofurazone Solution
 - Furacin Dusting Powder
 - Furacin Ear Solution
 - Furacin Solution Veterinary
 - Furacin-Microfur
 - Sulfamylon-N
 - Fura Ointment
 - Furaderm
 - Fura-Solution
 - Fura-Septin Soluble Dressing
 - Nitrofurazone Dressing
 - Fura-Vet
 - Nitrofurazone Anesthetic Dress.
 - Furacol Solution
 - Nitrozone Solution
 - Fura-Zone
 - Fura-Zone Solution
 - NFZ® Wound Dressing
 - Nitrofurazone Soluble Dressing
- Water: Furacin Soluble Powder

Novobiocin: (antimicrobial)

- Intrammary: Albamast® Suspension

Orbifloxacin: (antimicrobial-fluoroquinolone family) Extra label use prohibited in food animals

- Oral: Orbox™ Tablets

Oxytetracycline: (antimicrobial, tetracycline family)

- Injectable:
 - LA 200®
 - Liquamycin® Injectable
 - Terramycin® Injectable
- Oral
 - Terramycin® Animal Formula
 - Terramycin® Soluble Powder
 - Terramycin® Scour Tablets
 - MGA® (liquid) / Terramycin®

Penicillin: (antimicrobial-penicillin family beta lactam)

- Penicillin benzathine injectable:
 - Combicillin® AG
 - Dura-biotic
 - Longicil Fortified
 - Benza-Pen
 - Pen BP-48
 - Bicillin Fortified
- Procaine Penicillin G Injectable
 - Flo-cillin®
 - Agricillin Pen Aqueous
 - Aqua-Cillin; Penicillin G Co-op
 - Crystalline Pro Penicillin G
 - Crysticillin
 - Penicillin G Procaine
- Intramammary:
 - Albadry Plus® Suspension
 - Quartermaster® Dry Cow Treatment

Aqua-Mast
Hanfords Four-Pen
Formula A-34
Uni Biotic 4 Dose
Dry-Mast

Phenylbutazone: (NSAID) Prohibited in female dairy cows over 20 months of age

- Injection:
 - Butazolidin Injectable 20%
 - EquiBute Injection
 - Robizone-V Injection
- Oral:
 - Butazolidin Bolus
 - Butazolidin Tablets
 - Tevcodyne tablets
 - Bizolin®-100 tablets
 - Bizolin®-200 tablets
 - Robizone-V tablets

Pirlimycin: (antimicrobial, lincosamide family)

- Intramammary:
 - Pirsue® Aqueous Gel
 - Pirsue® Sterile Solution

Progesterone: (hormone, nonsynthetic)

- Implants:
 - Synovex®-C
 - Synovex®-S
 - Component® E-C with Tylan®
 - Component® E-S with Tylan®

- Intravaginal: EAZI-Breed™ CIDR® Cattle Insert

Ractopamine: (growth promotant, beta agonist) Approved for use in growing swine only. Not approved in cattle.

- Medicated Feed:
Paylean®; Paylean® 45
Paylean® / Tylan®

Salicylic Acid: (NSAID, aspirin)

- Bougie²: Shurjets
- Oral: None approved at this time

Spectinomycin: (antimicrobial, aminoglycoside family)

- Injectable:
Adspec® Sterile Solution
Spectam® Injectable
PROSPEC® Injectable
Spectinomycin Injectable
Spectinomycin Injection
- Oral:
Spectinomycin Tablet
Spectam® Scour Halt
Spectinomycin Oral Liquid
Spectam® Tablets
- Water
Spectam® Water Soluble Concentrate
L-S 50 Water Soluble® Powder

Streptomycin: (antimicrobial, aminoglycoside family)

- Bulk Drug: *Under AMDUCA, compounded drugs made from bulk illegal for use in Animal Drugs*

² Device for delivery of the drug-stays in teat canal till next milking
DATE OF ISSUANCE: August 1, 2005
MINOR CORRECTIONS: August 23, 2005
FORM FDA 2438

Dihydrostreptomycin Sulfate
Streptomycin Sulfate Bulk (Veterinary)

- Medicated Feed:
Rainbrook Broiler Premix No.1
- Oral:
Entromycin Powder
Entromycin Tablets No.1
Entromycin Tablets No.2
Streptomycin Oral Solution
Strep-Sol

Sulfadimethoxine: (antimicrobial, Sulfonamide)

- Injectable:
Albon®
Agribon Injection 40%
- Oral:
Albon®
Agribon Boluses - 2.5
Agribon Boluses - 5.0
Agribon Boluses - 15.0
Albon® S.R. (Sustained Release)
- Water:
Agribon 12.5% Drinking Water Solution
Di-Methox Antibacterial Soluble Powder
Sulfasol® Soluble Powder

Sulfabromomethazine: (antimicrobial, Sulfonamide)

- Oral: Sulfabrom 2.5 g

Sulfaethoxypyridazine: (antimicrobial, Sulfonamide)

- Injectable: S.E.Z. Intravenous Solution
- Oral: S.E.Z. Oblets 15 G
- Water: S.E.Z. Drinking Water Solution

Sulfamethazine: (antimicrobial, Sulfonamide) Extra label use prohibited in lactating dairy cows

- Injectable:
Sulmet® Solution Injectable
- Oral:
Tylocine Sulfa Tablets 50
HavaSpan Prolonged Release Bolus;
SulfaSpan Prolonged Release Bolus
Sulka-S™ Bolus
Sulfa Sustained Release Bolus
Calfspan™
Purina® Sulfa
Sulfamethazine Spanbolet II
Sustain III® Bolus
Sulmet® Oblets
Veta-Meth™
- Medicated Feed
Aureo SP-250; Aureomix 500
Aureomix S 700 Crumbles; Aureomix S 700 g
Tylan® 10 Sulfa-G Premix; Tylan® 40 Sulfa-G Premix
Aureomix S 700-A
Aureomix S 700-D
Aureomix S 700-G
Aureomix S 700-E
Aureomix S 700-F
Aureomix S 700-C-2

Aureomix S 700-B
Aureomix S 700-H
Purina® Pork-Plus Medicated
Chlorachel™ 250 Swine / Pficlor SP 250
ChlorMax™-SP 250; ChlorMax™-SP 500
ChlorMax™-SP 1000
CO-OP Tylosin 40 Plus Sulfamethazine
Tylan® 40 Plus Sulfa-G
Hubbard Tylan® Plus Sulfa Premix
Swine Med-A-Mix TS 8000 Premix
Tylan® 40 Sulfa-G
Tylan® 20 Sulfa-G
Tylan® 10 Sulfa-G
Tylan® 5 Sulfa-G
Quali-Tech Tylan®-Sulfa Premix 10 -10
Tylan® 5 Sulfa-G; Tylan® 10 Sulfa-G
Tylan® 20 Sulfa-G; Tylan® 40 Sulfa-G
Medi-Flex T:S
Tylan® Sulfa 10-10 Premix
Tylan® 5 Sulfa-G
Tylan® 10 Sulfa-G
Tylan® 20 Sulfa-G
Tylan® 40 Sulfa-G
Tylan® Sulfa 5 G
Tylan® Sulfa 10 G
Tylan® Sulfa 20 G
Tylan® Sulfa 40 G
Purina® Tylan® 40 Plus Sulfamethazine
Mill Co Medicator TS-40 Premix
Seeco Tylan®-Sulfa 10 Premix Med.
Tylan® 20 Sulfa-G

Tylan® 40 Sulfa-G
HFA Tylosin-10 Plus Sulfa
Tylan® 5 Sulfa-G
Tylan® 10 Sulfa-G
Tylan® 20 Sulfa-G
Tylan® 40 Sulfa-G
Tylan® 5 Sulfa-G
Tylan® 10 Sulfa-G
Tylan® 20 Sulfa-G
Tylan® 40 Sulfa-G
Tylan® 5 Sulfa-G
Tylan® 10 Sulfa-G
Tylan® 20 Sulfa-G
Tylan® 40 Sulfa-G
Tylan® 5 Sulfa-G
Tylan® 10 Sulfa-G
Tylan® 20 Sulfa-G
Tylan® 40 Sulfa-G
Nutra-Mix Tylan®-Sulfa Premixes
Heinold Tylan® 5 Sulfa Premix
Tylan® 5 Sulfa-G
Tylan® 10 Sulfa-G
Tylan® 20 Sulfa-G
Tylan® 40 Sulfa-G
Tylan® 5 Sulfa-G
Tylan® 10 Sulfa-G
Tylan® 20 Sulfa-G
Tylan® 40 Sulfa-G
Tylan® Sulfa
Tylan® 5 Sulfa Premix
Tylan® 10 Sulfa Premix

Tylan® 5 Sulfa Premix
Tylan® 5 Sulfa-G
Tylan® 10 Sulfa-G
Tylan® 20 Sulfa-G
Tylan® 40 Sulfa-G
Tylan® 5 Sulfa-G
Tylan® 10 Sulfa-G
Tylan® 20 Sulfa-G
Tylan® 40 Sulfa-G
Nutra-Blend Tylan® 5 Sulfa Premix
Tylan® 5 Sulfa Premix
Tylan® 10 Sulfa Premix
Tylan® 20 Sulfa Premix
Tylan® 40 Sulfa Premix
Tylan® 5 Sulfa-G
Tylan® 5 Sulfa Premix
Tylan® 10 Sulfa-G
Tylan® 20 Sulfa-G
Tylan® 40 Sulfa-G
Tylan® 5 Sulfa-G
Tylan® 10 Sulfa-G
Tylan® 20 Sulfa-G
Tylan® 40 Sulfa-G
Tylan® Sulfa-G
Tylan® Sulfa-G
Tylan® 5 Sulfa-G Premix
Tylan® 10 Sulfa-G Premix
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Tylan 40 Sulfa-G
Tylan® 5 Sulfa-G Premix
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Tylan® 20 Sulfa-G Premix
Tylan® 40 Sulfa-G Premix
Tylan® 5 Sulfa-G Premix
Tylan® 10 Sulfa-G Premix
Tylan® 20 Sulfa-G Premix
Tylan® 40 Sulfa-G Premix

- Water
 - Sulmet® Drinking Water Solution
 - Aureomycin® Sulmet Soluble Powder
 - Aureo Sulfa Soluble Powder
 - Sulmet® Soluble Powder

Sulfachlorpyridazine: (antimicrobial, sulfonamide) Extra label use prohibited in lactating dairy cows

- Oral:
 - Prinzone Bolus
 - Pyradan Bolus
 - Vetisulid® Bolus
 - Vetisulid® Tablets
 - Prinzone Oral Suspension
 - Pyradan Oral Suspension
 - Vetisulid® Oral Suspension
- Injection:
 - Prinzone Injection
 - Pyradan Injection
 - Vetisulid® Injection
- Water:
 - Prinzone Powder
 - Pyradan Powder
 - Vetisulid® Powder

Sulfamethoxazole: (antimicrobial, sulfonamide-no current approvals) Extra label use prohibited in lactating dairy cows

Sulfadiazine/trimethoprim: (antimicrobial, potentiated sulfonamide) Extra label use prohibited in lactating dairy cows

- Injectable: Tribrisen® 48% Injection
- Oral:
 - Tribrisen® 30 Tablets
 - Tribrisen® 120 Tablets
 - Tribrisen® 480 Tablets
 - Tribrisen® 960 Tablets
 - Tribrisen® 400 Oral Paste
 - Tucoprim® Powder
 - Sulfa Di-Trim® Tablets

Testosterone Propionate: (hormone)

- Implant: Synovex®-H

Tetracycline: (antimicrobial, tetracycline family)

- Oral
 - Panmycin® 500 Bolus
 - Polyotic® Oblets®
 - Tet-Sol 10
 - Tet-Sol 324™

Tilmicosin: (antimicrobial, macrolide family)

- Injectable: Micotil® 300
- Medicated Feed: Pulmotil®

Trenbolone Acetate: (hormone, synthetic "androgenic" anabolic steroid)

- Implant: Finaplix®-H Finaplix®-S Revalor®-G
Revalor®-S
Revalor®-200
Revalor®-H
Revalor®-IH, Synovex® Plus
Component® TE-G with Tylan®
Component® TE-S with Tylan

Trichlormethiazide: (diuretic)

- Oral: Naquasone® Bolus (also contains dexamethasone)

**Tripelennamine Hydrochloride (antihistamine) Human approved drug is called
PBZ®**

- Injectable: Recovr® Injectable

Tylosin: (antimicrobial, macrolide family)

- Injectable: Tylan®, Tylosin® Injection
- Medicated Feed: **See Sulfamethazine under Feeds**
Tylan® 40 CAL Type A Medicated Article
Tylan® 100 CAL Type A Medicated Article
Tylan® Soluble, Tylan® 100 Premix
CO-OP Tylan® 10 Mix
Tylosin® 5 Type A Medicated Article
Tylosin® 10 Type A Medicated Article
Tylosin® 20 Type A Medicated Article
Tylosin® 40 Type A
Quali-Tech Tylan®-10 Premix
Tylan® 5 Sulfa-G
Tylan® 10 Sulfa-G
Tylan® 20 Sulfa-G

Tylan® 40 Sulfa-G

Xylazine (sedative, nonopioid)

- Injectable:
Rompun® Injectable (20 mg)
Rompun® Injectable (100 mg)
Anased®; Anased® Injectable
Xylazine HCl Injection
Sedazine™
Chanazine®
Chanazine®

Zeranol (hormone, synthetic “estrogenic” anabolic steroid)

- Implants:
Ralgro® Implants
Ralgro® Magnum

Additional Drugs:

Explanation of terms used in entries and footnotes:

Example:

Gentamicin: (antimicrobial)

- Dip (turkey eggs): Garasol® Solution, Gentasol

Antimicrobial is a broad term that includes drugs that kill or inhibit bacteria. Gentamicin is “cidal”, i.e. kills bacteria susceptible to it.

Garasol® is the drug “**trade name**” : designated by the “®”. **An approved new animal drug always has an NADA (new animal drug application) number on the labeling!** Note that the approved use should also be on the labeling.

Gentamicin is the “**established name**” for this drug. Sometimes “established name” is used interchangeably with the term “generic”, and they are not necessarily the same thing.

Generic: This term is used 2 ways-

1. used interchangeably with term “established name” for a drug.
2. a “**Generic Drug**”: an FDA approved generic drug . Requirements for approval of an ANADA (abbreviated new animal drug application) include: the “pioneer” drug has to be off patent and still considered safe and effective; generic has to be an *exact* copy of the “pioneer” including its manufacturing, claims, etc. Generic copies generally do not have “®” after the name, and sometimes the drug established name is the only name given on the bottle, i.e. gentamicin sulfate. **An approved Generic Drug always has an ANADA number on the labeling!**

Pioneer Drug: These drugs are from the sponsor’s original approval, often the first trade name to come on the market for a particular drug entity. The “pioneer”, or first, drug approved for a particular drug entity has patents and other protections so that “generic copies” cannot be made for several years following the original approval. **In the case of gentamicin**, Schering-Plough has the original approvals-the “pioneer products” with tradenames **Garasol®**, **Garacin®**, **Gentocin®**.

AMDUCA Prohibited Drugs List http://www.fda.gov/cvm/Documents/530_41.txt

The following drugs (both animal and human), families of drugs, and substances are prohibited for extra-label uses in all food-producing animals:

- Chloramphenicol;
- Clenbuterol;
- Diethylstilbestrol (DES);
- Dimetridazole;
- Iprnidazole;
- Other nitroimidazoles (i.e. metronidazole);
- Furazolidone, Nitrofurazone, other nitrofurans;
- Sulfonamide drugs in lactating dairy cattle (except approved use of sulfadimethoxine, sulfabromomethazine, and sulfaethoxypyridazine);
- Fluoroquinolones (enrofloxacin, danofloxacin, orbifloxacin)
- Glycopeptides (vancomycin, teicoplanin, oritavancin)
- Phenylbutazone (in female dairy cattle 20 months of age or older)

Compounded Drugs:

- FDA defines compounding as the manipulation of drugs to obtain products that differ from the starting materials in an approved dosage form drug. **Under AMDUCA, compounding is considered to be extra-label drug use, and must be done from approved finished dosage form drugs only.**
- It is illegal for veterinarians, or pharmacists, to compound unapproved finished new animal drug products from *bulk* drugs.
- **Non-commercial labels may serve as a cue for identifying compounded products.**

ATTACHMENT H - District Monitor Checklist

RVIS Activities

- Review Weekly Report for assignment
- Check RVIS for addl. residues prior to insp.
- Provide State with computer-generated Attachment C forms prior to inspection
- Enter appropriate follow-up activity codes
- Each Fed/State inspec. must have an FDA responsibility code entered (R, I, N)
- Enter activity codes for Enforcement Actions
 - Periodically run reports to identify specific violation/violator trends/patterns
- Twice per year provide District mgmt. with list of Repeat Violators
- Review the "Not Investigated Repeat Violator Report" to make sure none of your DO's firms are on the report.
- Review the "Investigated w/No Responsibility Code Entered Report" to make sure none of your DO's firms are on the report.

Administrative Activities

- Promptly issue assignments for Fed/State inspections per CP guidelines
- Remind all to complete the Drug Inventory Survey
- Review completed EIR's for changes to firm info.
- Enter firm change information into RVIS.
- Review Attachment C's for completeness (IF not complete, contact FDA investigator or State Coordinator and explain what should have been completed in effort to improve quality of future rpts.
- Request Regulatory Reserve Samples for firms possibly subject of an enforcement action.
- Monitors should maintain a list of samples that they have requested to be stored in an FDA laboratory. Periodically review this list and request a Sample Destruction Notices (SDNs) be prepared through the appropriate channels in your District once it becomes clear that the District will not be initiating enforcement action against a firm.
- For all Federal and State investigations/inspections submit to HFV-235 a copy of the FACTS coversheet w/ endorsement, and Attachments C & G.
- Work with CVM to distribute industry outreach materials to address local residue concerns.
- Serve as a clearinghouse for distribution of pertinent information to cooperating State Officials and District Mgmt.
- Recommend training of al Fed/State personnel conducting residue investigations.
- Maintain routine communications with local reps. Form FSIS, APHIS, GIPSA and the States.