CHAPTER 04 - PESTICIDES AND CHEMICAL CONTAMINANTS

SUBJECT:	**IMPLEMENTATION DATE**
Chemotherapeutics in Seafood Compliance Program *(FY 09/10/11)*	10/01/08
	COMPLETION DATE 09/30/11 or until revised

DATA REPORTING

PRODUCT CODES	PRODUCT/ASSIGNMENT CODES
INDUSTRY CODES: 16 PRODUCT CODES: *Basa* or other *Pangasius* species 16X[][]43 Catfish 16X[][]02 Crabmeat 16J[][]01 Crawfish 16X[][]20 *Eel* 16A[][]15 Salmon 16X[][]03 Shrimp 16X[][]21 Tilapia 16X[][]06 *Trout* 16X[][]03	REPORT COLLECTIONS AND ANALYSES USING PAC: 04018

Note: Material this is not releasable under the Freedom of Information Act (FOIA) has been redacted/deleted from this electronic version of the program. Deletions are marked as follows: (#) denotes one or more words were deleted, (&) denotes one or more paragraphs were deleted, and (%) denotes an entire attachment was deleted.

FIELD REPORTS TO HEADQUARTERS

A. There are no hard copy reports for this Compliance Program.

B. Resources for completion of this Compliance Program can be found in the current ORA Field Workplan under PAC 04018, Chemotherapeutics in Seafood Compliance Program.

C. FACTS/OASIS reporting for domestic and import sample collections and for domestic and import sample analyses:

1. PAC: 04018
2. PAF: ANT

PART I - BACKGROUND

Over the past twenty years, there has been an extensive commercialization and an increased consumption rate of aquaculture seafood products. The worldwide consumption has increased from 6.7 million metric tons in 1984 to 48.2 million metric tons in 2006 (FAO: Fishery & Aquaculture Department in The State of World Fisheries and Aquaculture, 2007).

As this industry grows, the use of unapproved and/or the misuse of FDA approved new animal drugs administered to aquaculture seafood also grows. To protect consumers it is important to ensure that both imported and domestic aquaculture seafood products are free from potentially harmful drug residues. Drug residues in food can cause acute, chronic or microbial effects on people.

An acute response can occur from hypersensitivity or allergenicity from the drug such as penicillin. Documented acute responses to drug residues are the cases in Spain and France and China where people had consumed liver with clenbuterol residues became seriously ill.

Chronic effects can be long term and they are difficult to detect because these events are typically underreported. Cancer is considered a potential chronic long term effect of drug residues.

Microbial effects of drug residues can have an effect on human intestinal flora which can diminish the activity of intestinal bacteria. Another effect of antibiotic drug residues can be the development of transient resistant populations. For example, the unapproved use of fluoroquinolones, such as ciprofloxacin, poses the risk of increasing antibiotic resistant bacteria with the potential for serious human health consequences from untreatable infections. In addition, chronic dietary exposure to high concentrations of fluoroquinolone residues, particularly during early growth, may result in a number of toxicities including joint and testicular lesions. The use of compounds not approved in the US, or the misuse of FDA approved new animal drugs, will have an impact on the safety of aquaculture products for consumers.

PART II - IMPLEMENTATION

OBJECTIVE

To sample and analyze selected import and domestic aquaculture seafood products and crabmeat to determine the presence of unapproved chemical compounds or the presence of unapproved new animal drugs such as antibiotics or anti-fungals

APPROACH

This compliance program is based on the collection of samples of aquaculture seafood products, and also includes processed crabmeat and “eel”. Any samples found to contain unapproved chemotherapeutics agents may lead to follow-up investigations at suspect firms. During sample collection of domestic product, if the investigator suspects that an unapproved new animal drug is being used, evidence of the intended use should be obtained if possible at the point of sample collection. CVM may issue an assignment in order to document the use of the unapproved new animal drugs for possible enforcement action. CVM will also issue an assignment for follow-up to reports of positive drug residues.

INTERACTION WITH OTHER PROGRAMS

- Illegal Drug Residues in Meat, Poultry, Aquacultured Seafood and other Animal Derived Foods Compliance Program, 7371.006: Follow the instructions to conduct on-farm investigations or investigations at a veterinarian or any other involved parties for drug residues from domestically produced product.

- Import Seafood Products Compliance Program, 7303.844: Use as a guide to conduct follow-up investigations at importers.

- Domestic Fish and Fishery Products Inspection Program, 7303.842: Use for aquaculture seafood concerns other than chemotherapeutic agents.

- Aquaculture seafood products are also collected for Dioxin analysis as part of Pesticides and Industrial Chemicals in Domestic and Imported Foods Compliance Program (7304.004). Districts may coordinate sample collections as appropriate.

PART III - INSPECTIONAL

A. Sample Collection

1. Collecting Districts: Refer to the current FY ORA Field Workplan and the current FY Collection Schedule issued by CFSAN before the start of each fiscal year for specific numbers of species to collect. #

   Note: Only those products listed in the current collection schedule should be collected.

2. Examples of the products to be collected:

Domestic	Import
Catfish Crabmeat Crawfish Salmon Shrimp Tilapia *Trout*	*Basa* and other *Pangasius* Species Channel Catfish Crabmeat Crawfish *Eel* Salmon Shrimp Tilapia *Trout*

NOTE: See Import Alert #16-128, "Misbranded Catfish" for the correct naming of import fish belonging to the Non-Ictaluridae Family of catfish.

3. Sampling Instructions

   For the purpose of this Compliance Program, aquaculture is the breeding, rearing and harvesting of aquatic food animals under environmentally controlled conditions. Samples should be collected from the largest lots available. Attempt to sample lots having the smallest unit packages whenever possible. Raw, unprocessed, breaded, fresh, or frozen product is acceptable for collection unless otherwise specified in the current FY Collection Schedule. *Canned product except for crabmeat should not be collected.* Samples that are collected "fresh" can be frozen. Frozen, pasteurized, or canned crabmeat (typically in pound cans) should be collected. Fresh crabmeat is acceptable, but whole crab should not be collected. Crawfish is cooked and typically packed in plastic bags (lbs.). When collecting any fresh product, the investigator should coordinate with the assigned laboratory so that the applicable timeframes are met.

   Domestic Sample Collections

   Refer to current FY Collection Schedule for the number of domestic samples to be collected of each product.

   All products except for crabmeat and crawfish must be aquaculture raised. Crab and crayfish can be collected if aquaculture or wild caught.

A review of the firm's EIR jacket or a phone call is acceptable to determine if the firm does grow the desired aquaculture product. Samples should be collected as near to the point of harvest as possible. Domestic shrimp samples may be collected from processors or wholesalers provided that the domestic grower can be identified in the collection report.

Please verify that product is not originally from a foreign source. If the investigator discovers that the original product comes from (or is commingled with) a foreign source, follow the instructions for Import Sample Collections.

Import Sample Collections

Refer to current FY Collection Schedule for the number of import samples to be collected of each product and for countries of interest.

*Import seafood may not be identified on labeling or in shipping documents as "Aquaculture Products." It should be assumed that catfish/basa, shrimp, and tilapia are farm raised unless accompanying paperwork/labeling states “wild caught”. The collecting district should only sample those entries of salmon and *trout* which can be verified as aquaculture products. Crabmeat, crayfish and eel may be collected if it is “wild caught” or farm-raised.*

The investigator should notify the lab that fresh seafood is on hold pending completion of analysis by annotating the FDA 525 and using the appropriate sample flag on the Collection Report. Fresh imported product may be collected in domestic/import sample so that the product will not be in danger of spoiling before it can be analyzed. When this is done, the collector must include the OASIS entry number in the remarks section of the Collection Report.

Import obligations may be met by collecting samples in Domestic Import (DI) status only if the district can identify the foreign processor/shipper, and the country of origin. DI samples should not be counted as part of the domestic sample obligations. DI samples should be collected as per the sample size guidance for Domestic Samples.

The collecting districts are encouraged to work with the Division of Import Operations and Policy (DIOP), #

4. Sample Sizes

Domestic and Domestic/Import Samples

Catfish, Salmon, Tilapia, *Trout*	Each fresh or frozen sample collected from a single lot should consist of 12 subsamples, weighing at least 454 gm (1 lb.) per subsample, for a total weight of 5.4 kg (12 lb.) per sample. The 454 gm (1-lb.) subsamples include the 702(b) portion.
Shrimp	Collect twelve (12) subsamples, minimum 454 g (1.0 lb.) per subsample. The 454 gm (1-lb.) subsamples include the 702(b) portion.
Crabmeat, Crawfish	Each sample should consist of twelve (12) subsamples, minimum 225 g (0.5 lb.) per subsample, total 2.7 kg (6.0 lb.) of product. If the product unit size is larger than 225 g (0.5 lb.) and less than or equal to 3 lb., collect one product unit per subsample. If the unit size is less than 225 g (0.5 lb.), collect an adequate number of units so that the amount collected per subsample equals a minimum of 225 g (0.5 lb.). These sample sizes already include the 702(b) reserve for domestic crabmeat/crawfish.

Import Samples

Basa, Catfish, *Eel*, Salmon, Tilapia, *Trout*	Each sample should consist of 12 - 225 gram (0.5 lb.) subsamples, totaling 2.7 kg (6.0 lb.) of product. If the container size is larger than 225 grams (0.5 lb.), collect one container per subsample. If the container is less than 225 grams (1/2 lb.), collect an adequate number of containers so that the amount collected per subsample equals a minimum of 225 grams (1/2 lb.). Note: For import salmon collections only – In situations where a district feels the cost of above sample sizes is prohibitive, the following alternate sampling scheme may be applied (all subs still equal ½ lb.): 12 subs for salmon < 3 lbs, 6 subs for salmon <6 lbs and 3 subs for larger salmon. The labs will make a single composite from equal portions of each sub received.
Crabmeat, Crawfish, Shrimp	Each sample should consist of twelve (12) subsamples, minimum 225 g (0.5 lb.) per subsample, total 2.7 kg (6.0 lb.) of product. If the product unit size is larger than 225 g (0.5 lb.) and less than or equal to 3 lb., collect one product unit per subsample. If the unit size is less than 225 g (0.5 lb.), collect an adequate number of units so that the amount collected per subsample equals a minimum of 225 g (0.5 lb.). Note: For <u>units larger than 3 lb. only</u>: If the units must be sampled and shipped intact, collect 6 subsamples (units) and send to assigned laboratory. Alternatively, subsamples of at least 225 g (0.5 lb.) may be broken/sawed off (keep frozen) from each of 12 units, and the twelve (12) 225 g subsamples shipped to the analyzing lab. If sampling from bulk, collect using aseptic technique (refer to IOM 426).

B. SHIPPING INSTRUCTIONS

Shipping instructions to maintain the integrity of frozen and refrigerated samples and the procedure to notify the receiving laboratory can be found in IOM, Sections 4.5.3.5, 4.5.3.6, and 4.5.5.5. Samples should be packaged with the appropriate refrigerant and shipped so that they arrive at the laboratory no later than Thursday of each week.

Samples should only be shipped to the assigned laboratory designated in the current FY Collection Schedule. Because not all laboratories are set up to analyze the targeted chemotherapeutic agents, it may not be possible to use the National Sample Distribution (NSD) system. If NSD specifies shipping a sample to a lab that is not listed in the current FY Sample Collection Schedule, the NSD must be overrode and the sample sent to a lab capable of testing for the target residue.

PART IV - ANALYTICAL

A. ANALYZING LABORATORIES

Refer to current FY Collection Schedule to determine which laboratories can be utilized.

For residues requiring both determinative and confirmatory methods, the laboratory performing the determinative method has the option of performing the confirmatory testing on presumptive violations or sending it to Denver Laboratory at the following address:

Denver District Laboratory
ATTN: Sample Custodian (303) 236-3068
6th Avenue and Kipling St.
DFC, Building 20, ENT W-10
Denver, CO 80225-0087

The laboratory performing the determinative testing will be responsible for promptly reporting illegal residue findings (sample number, collection date, analytical results, and confirmatory results) to the collecting district.

B. ANALYSIS – Sample Preparation and Methods

1. General Instructions

None of the chemical compounds identified in the following methods are permitted for use in combination with the seafood species identified for sampling and analysis in this Compliance Program. The determinative method will identify and quantify the amount of the compound and the confirmation method will validate findings of the determinative method (if applicable). Therefore, no further analyses are required.

Report all analytical results in FACTS. #

2. Analytical Protocol

Prepare one composite of all subsamples, unless otherwise noted for specific products requiring individual sub sample analysis.

The determinative method should be run on all samples. Whenever the analytical result of the residue from the determinative method is equal to or above the level referenced below (under C. **LEVELS of CONFIRMATION)** for each species-drug combination, a confirmative method must be run (where applicable). The confirmative method for each residue/species combination employs mass spectrometry detection to confirm the identity of the residue.

NOTE: Chloramphenicol (CAP) analysis is confirmation (mass spectrometry based) testing and no determinative procedure is provided.

#

3. **Sample Preparation**:

For catfish/basa, *eel*, salmon, tilapia, and *trout*: Homogenize edible portion. It is suggested that laboratories homogenize sample by grinding with dry ice (reference: Bunch, E.A., Altwein, D.M., Johnson, L.E. Farley, J.R., and Hammersmith, A.A. (1995) Homogenous Sample Preparation of Raw Shrimp with the Aid of Dry Ice. *J. AOAC Int*. 78, 883-887.

For domestic samples retain 225 g as the 702(b) portion from each of the 12 fish samples in the lot.

For crabmeat/crawfish for CAP and for shrimp for CAP and Nitrofurans: All CAP analyses for all products are to be run on an individual sub basis. All nitrofurans analysis for shrimp is to be run on an individual sub basis. The confirmation of chloramphenicol or nitrofurans in a single subsample is sufficient to establish presence. The lab is to continue analyzing individual subsamples until either chloramphenicol or nitrofurans is confirmed in a subsample portion, or a total of 12 negative subsample portions are completed. If 12 subsamples are collected (3 lb or less per unit), select at random approximately 100 grams of product (chipped from block if frozen) from each subsample. If 6 subsamples (>3 lb units) were collected, analyze individually each of two (2) 100 g portions, taking the portions from opposite ends of the subsample. Shell product and exercise care to exclude all shells from sample. It is suggested that laboratories homogenize sample by grinding with dry ice (see reference above). Divide the prepared sample in half. Use half of the prepared sample for the original analysis and retain the other half of the prepared sample in a freezer as a reserve.

For shrimp for all other residues*:* Prepare one composite by combining portions of all subsamples. If 12 subsamples are collected (3 lb. or less per unit), select at random approximately 100 grams of shrimp (chipped from block if frozen) from each subsample. Thoroughly remove any breading before analysis. If 6 subsamples (>3 lb. units) were collected, select randomly two 100 g portions taken from opposite ends of the subsample for the composite. It is suggested that laboratories homogenize sample by grinding with dry ice (see reference above.) Divide the prepared sample in half. Use half of the prepared sample for the original analysis and retain the other half of the prepared sample in a freezer as a reserve.

4. **Methodology**

Refer to the current FY Collection Schedule for priority of residues to be tested for each species.

It is very important that when results are entered into FACTS, the PAF = ANT must be used.

In the following table, hyperlinks when available have been provided for methods. Where there is no hyperlink and when a lab does not have access to the referenced method, they should contact Lawrence A D'Hoostelaere, DFS, at 301-827-1032 or e-mail him at Lawrence.dhoostllare@fda.hhs.gov for a copy of the method.

Product	Residue	Method	Published
Crabmeat; Crawfish; Shrimp	Chloramphenicol (CAP)	• LC/MS/MS Analysis of Chloramphenicol in Crab Meat LIB 4302 (2003) • LC/MS/MS Analysis of Chloramphenicol in Crawfish Meat LIB 4303 (2003) • Determination of Chloramphenicol Residues in Shrimp and Crab Tissues by Electrospray Triple Quadrupole LC/MS/MS LIB 4306 (2003)	
Shrimp	Chloramphenicol (CAP)	• LC/MS/MS Analysis of Chloramphenicol in Shrimp LIB 4290 2002	
Catfish/ Basa; Salmon; Shrimp	Fluoroquinolones (FQ)	**Determinative:** Concurrent Determination of Four Fluoroquinolones; Ciprofloxacin, Enrofloxacin, Sarafloxacin and Difloxacin in Atlantic Salmon Tissue by LC with Fluorescence Detection	Based on J. AOAC Int., 2002, 85 (6)1293-1301. Revised SOP issued by CVM October 24, 2003
Catfish/ Basa; Tilapia; Shrimp	Fluoroquinolones	**Determination** of four fluoroquinolones by liquid chromatography with fluorescence detection in catfish, shrimp, salmon, and tilapia LIB4408B	
Catfish/ Basa; Salmon; Tilapia; Shrimp	Fluoroquinolones	**Confirmatory:** "Confirmation of Fluoroquinolones in Catfish by Electrospray LC/MS"	LIB 4108 (1997)
		"Confirmation of fluoroquinolone residues in salmon and shrimp tissue by LC/MS: Evaluation of single quadrupole and ion trap instruments" LIB 4298 (2003	
Catfish/ Basa; Tilapia	Fluoroquinolones	• Rapid Extraction of Four Fluoroquinolones from Finfish with Acetonitrile Extraction and Hexane Clean-up: **Determination and Confirmation** by Liquid Chromatography/Fluorescence Detection and Liquid Chromatography/Tandem Mass Spectrometry LIB 4405 (2007)	
Catfish/ Basa; Tilapia	Fluoroquinolones	• Rapid Extraction of Four Fluoroquinolones from Finfish using Acetonitrile Extraction and Dispersive SPE Clean-up: **Determination** and **Confirmation** by Liquid Chromatography/Fluorescence Detection and Liquid Chromatography/Tandem Mass Spectrometry LIB 4404 (2007)	
Salmon; *Trout*	Ivermectin	Determinative: LC Fluorescence Determination of Ivermectin in Salmon Muscle Tissue	Dec. 31 2002
Salmon; *Trout*	Ivermectin	**Determinative:** "Determination of Ivermectin in Salmon Muscle Tissue by Liquid Chromatography with Fluorescence Detection"	J. AOAC Int. Vol. 81, No. 3, 1998 p549-553
Salmon; *Trout*	Ivermectin	• **Confirmatory:** "Confirmation of Ivermectin Residues in Food Matrices with Negative Ion Atmospheric Pressure Chemical Ionization LC/MS" LIB 4158 (1999)	

Product	Residue	Method	Published
Salmon; *Trout*	Ivermectin	• **Determination** of Ivermectin in Salmon using the QuEChERS Method LIB 4374 (2006)	
Catfish/ Basa; *Eel*; Salmon; *Trout*; Tilapia	Malachite Green (MG)	• **Quantitative** and **Confirmatory** Analysis of Malachite Green and Leucomalachite Green Residues in Fish and Shrimp LIB 4363 (2005)	
	Crystal (gentian) violet (GV)	• **Quantitative** and **Confirmatory** Analysis of Crystal Violet (Gentian Violet) and Brilliant Green in Fish LIB 4395 (2007)	
Salmon; *Trout*	Malachite Green and Leucomalachite Green	• Determination of Malachite Green and Leucomalachite Green in Salmon with In-Situ Oxidation and Liquid Chromatography with Visible Detection LIB 4334	
	Leucomalachite Green	• Determination and Confirmation of Leucomalachite Green in Salmon using No-Charge Atmospheric Pressure Chemical Ionization LC-MS LIB 4333	
Tilapia	methyl-testosterone	LC-MS/MS **Determinative** and **Confirmatory** Assays of 17 alpha-methyltestosterone in Fish	CVM Study 301:55, version 1.00, Nov. 28-05
Tilapia	methyl-testosterone	ELISA Screening for Methyl-testosterone Residue in Tilapia Tissue	LIB pending
Shrimp	Multi-class, multi-residue	LC/MSn **Screening** for Multi-Class Drug Residues in Shrimp	CVM Study 301.58 V3; also J. Chromatography B (2006) 836 22-38
Catfish/ Basa	Nitrofurans	Residue Depletion of Nitrofuran Drugs and Their Tissue-Bound Metabolites in Channel Catfish (*Ictalurus punctatus*) after Oral Dosing	
Shrimp	Nitrofurans	• A Liquid Chromatography Method for the Detection of Nitrofuran Metabolites in Shrimp	
Catfish/ Basa, Shrimp	Quinolones	**Determinative** procedure: "Determination of Flumequine, Nalidixic, Oxolinic and Piromidic Acid Residues in Aquatic Species by High Performance Liquid Chromatography-Fluorescence/UV Detection,"	Dated September 23, 1996.
Catfish/ Basa, Shrimp	Quinolones	"**Confirmation** of Flumequine, Nalidixic, Oxolinic, and Piromidic acid in Catfish Tissue by GC/MS"	
Catfish/ Basa; Salmon; Shrimp; *Trout*	Quinolones	"Oxolinic Acid and Flumequine Residues in Shrimp by HPLC with Fluorescence Detection" LIB 4336 (2004)	
Catfish/ Basa; Salmon; Shrimp;	Quinolones	**Confirmation** of Oxolinic acid, Flumequine, and Nalidixic acid in Shrimp using Liquid Chromatography Electrospray Mass Spectrometry LIB 4383 (2006)	

Product	Residue	Method	Published
Trout			
Salmon; *Trout*	Oxolinic Acid	Determination of Oxolinic Acid residues in Salmon Muscle by Liquid Chromatography with Fluorescence Detection	J. AOAC Int. 74(4) 1991 p 608-611
Salmon; *Trout*	Oxolinic Acid	Confirmation of Incurred Residue of Flumequine, Nalidixic, Oxolinic and Piromidic Acids in Shrimp and Salmon	LIB 4039 1996

C. LEVELS of CONFIRMATION

The following values are the current limit of detection for each method supported by CVM as sufficient for detecting the presence of each residue.

Species	Residue	Confirmation Level (ppb)
Catfish and *Basa* and other *Pangasius* Species	Malachite Green/Genetian Violet	#
	Fluoroquinolones	#
	Quinolones (Oxolinic Acid, Flumequine)	#
	Nitrofurans	#
Crabmeat/Crawfish	Chloramphenicol	#
Salmon	Ivermectin	#
	Oxolinic Acid	#
	Flumequine	#
	Malachite Green	#
Shrimp	Chloramphenicol	#
	Fluoroquinolones	#
	Nitrofurans	#
	Quinolones (Oxolinic Acid, Flumequine)	#
Tilapia	Malachite Green	#
	Fluoroquinolones	#
	Methyltestosterone	#

PART V - REGULATORY/ADMINISTRATIVE STRATEGY

Samples must meet the following criteria to be submitted to DIOP/CFSAN:

- Sample was collected consistent with the instructions in Part III, Inspectional, A. Sample Collection and the minimum sample size is met.
- Sample preparation and analytical methods used are only those listed under Part IV, Analytical, B. Analysis, 4. Methodology.
- The presence and confirmation (if applicable) of the residue found in any sample is at a level greater than or equal to the level of confirmation listed in Part IV, Analytical, C. Levels of Confirmation.

Import Compliance Actions:

If the presence of a drug residue is confirmed by the analysis of an import sample, the district should refer to the appropriate Import Alert (IA) below for relevant charges when submitting recommendations to DIOP:

General Unapproved Drugs in Seafood Import Alert #16-124
DETENTION WITHOUT PHYSICAL EXAMINATION OF AQUACULTURE SEAFOOD PRODUCTS DUE TO UNAPPROVED DRUGS

Chloramphenicol in Crabmeat Import Alert #16-127
DETENTION WITHOUT PHYSICAL EXAMINATION OF CRABMEAT DUE TO CHLORAMPHENICOL

Nitrofurans in Seafood Import Alert #16-129
DETENTION WITHOUT PHYSICAL EXAMINATION OF SEAFOOD PRODUCTS DUE TO NITROFURANS

The District should refer to any additional instructions in the Regulatory Procedures Manual, Chapter 9.

The home district of the importer should consider a follow-up HACCP Inspection, per the Import Seafood Products Compliance Program, 7303.844, at the importer whose products were found to contain illegal residues.

Domestic Compliance Actions:

At this time, all domestic compliance actions should be discussed with CFSAN's OC/Division of Enforcement who will coordinate regulatory follow-up with CVM.

CVM Violative Sample Guidance for Domestic Seafood Products

If a drug residue is confirmed in domestic produced seafood, CVM will take the lead on providing direction to determine the cause of the residue. Use Compliance Program, 7371.006, Illegal Drug Residue in Meat, Poultry, Aquacultured Seafood and other Animal Derived Proteins to conduct investigations of producers and other involved parties as appropriate. All the residues of the drugs that are being tested are unapproved new animal drugs; therefore, CVM will consider enforcement action for any violative residues when the responsibility, jurisdiction and violation are all documented.

CVM General and Regulatory Contact: Fran Pell, (240) 276-9211, frances.pell@fda.hhs.gov

Send copies of the EIR, FDA 483, and coversheet to CVM, OSC, Division of Compliance, HFV-235, Attention: Fran Pell.

PART VI - REFERENCES AND PROGRAM CONTACTS

REFERENCES

FDA/ORA Regulatory Procedures Manual (Including updates)
Investigations Operations Manual (most current)

PROGRAM CONTACTS

CFSAN

Program Contact:	Andrea Lee Wade	CFSAN, Office of Compliance, Division of Field Programs and Guidance, Field Programs Branch, HFS-615, (301) 436-2079, Fax (301) 436-2657, andrea.wade@fda.hhs.gov*
Regulatory Contact:	Salvatore Evola	CFSAN, Office of Compliance, Division of Enforcement, Product Adulteration Branch, HFS-606, (301) 436-2164, salvatore.evola@fda.hhs.gov
Scientific Contact:	Barbara Montwill	CFSAN, Office of Food Safety, OFS, Division of Seafood Safety, HFS-416, (301) 436-1426, barbara.montwill@fda.hhs.gov

CVM Technical and Regulatory Contact:	Fran Pell	CVM, OSC, Division of Compliance, Compliance Information Management Team, HFV-235, (240) 276-9211, frances.pell@fda.hhs.gov

ORA

Import Operations	Ted Poplawski	ORO, DIOP, Policy and Enforcement Branch, HFC-172, (301) 594-3849, tpoplaws@fda.hhs.gov
Domestic Investigations	Norman Fogg	ORO, DFI, HFC-130, (301) 827-5645, nfogg@fda.hhs.gov*
Scientific Contact	Lawrence D'Hoostelaere,	ORO, DFS, HFC-141, (301) 827-1032, lawrence.dhoostelaere@fda.hhs.gov

SCIENTIFIC METHOD ANALYSIS CONTACTS:

Note: ADRC – Animal Drug Research Center; Denver, CO

General CVM Method Contact:	Philip J. Kijak	CVM	301-210-4589
Chloramphenicol	Jim Stuart	PRL-NW	425-402-4880
	Joe Storey	DEN-LAB	303-236-9634
	Andrew Fong	ARL	870-453-4638
	Mary Carson	CVM/OR	301-210-4652
Fluoroquinolones	Susan Clark	DEN-LAB	303-236-9629
	Sarah McMullen	SRL	404-253-1200 ex 5370
	Sherri Turnipseed	ADRC	303-236-3072
	Hui Li	CVM/OR	301-210-4271
Mectins/Ivermectin	Heidi (Rupp) Marks	PRL	425-402-3164
	Sherri Turnipseed	ADRC	303-236-3072
	Badar Shaikh	CVM/OR	301-210-4654
Malachite Green/ Gentian Violet/ Leucomalachite	Wendy Anderson	ADRC	303-236-3074
	Sherri Turnipseed	ADRC	303-236-3072
Methyltesterone	Pak Chu	CVM/OR	301-210-4583
	Mayda Lopez	CVM/OR	301-210-4587
	Susan Clark	DEN-LAB	303-236-9629
Multi-class, multi-residue	Mary Carson	CVM/OR	301-210-4652
	Hui Li	CVM/OR	301-210-4271
Nitrofurans	Pak Chu	CVM/OR	301-210-4583
	Mayda Lopez	CVM/OR	301-210-4587
	Shaun MacMahon	NRL	718-340-7182
	Jack Lohne	NRL	718-340-7077
Quinolones	Christine Karbiwnyk	ADRC	303-236-3075
	Sarah McMullen	SRL	404-253-1200 ex 5370
	Sherri Turnipseed	ADRC	303-236-3072

PART VII - CENTER RESPONSIBILITIES

Program Evaluation

The Office of Food Safety has the responsibility to prepare periodic formal evaluations of this compliance program. #