CHAPTER 04 - PESTICIDES AND CHEMICAL CONTAMINANTS

SUBJECT:	**IMPLEMENTATION DATE**
Chemotherapeutics in Seafood Compliance Program *(FY 07/08)*	December 20, 2006
This program has completed A Good Guidance Practices clearance by CFSAN's ORP and OC/DFP/CPB in October of 2006.	**COMPLETION DATE** 09/30/09

DATA REPORTING

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

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 28.8 million metric tons in 1997 (FAO: Fishery Statistics, Catches and Landings, various years, FAO, Rome, Italy).

As this industry grows, the use of non-US approved and/or the misuse of limited US approved chemical compounds administered to aquaculture also grows. The use of compounds not approved in the US, or misuse of those with limited approval, 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 such as drugs or anti-fungals.

APPROACH

This compliance program is based on the collection of samples of aquaculture seafood products, and also includes processed crabmeat. 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 a chemotherapeutic agent is being used, evidence of the intended use should be obtained if possible at the point of sample collection. CVM may issue an assignment for any illegal use of chemotherapeutic agents.

INTERACTION WITH OTHER PROGRAMS

- Illegal Drug Residues in Meat and Poultry Compliance Program, 7371.006: Use as a guide to conduct on-farm investigations or investigations at a veterinarian's office, if applicable.
- Import Seafood Products Compliance Program, 7303.844: Use as a guide to conduct follow-up investigations at importers.
- 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. #

2. *Example products to be collected:

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

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 area acceptable for collection unless otherwise specified in the current FY Collection Schedule.* 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.

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, crabmeat (non-aquaculture), and crawfish samples may be collected from processors or wholesalers. 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." The collecting district should only sample those entries which can be verified as aquaculture products with the exception of crabmeat.

The investigator should notify the lab that fresh seafood is on hold pending completion of analysis by annotating the 525 and using the appropriate sample flag on the Collection Report.

Import obligations may be met by collecting samples in Domestic Import (DI) status 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 Samples	
Catfish, Salmon, Tilapia	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 225 g (0.5 lb.) per subsample, in DUPLICATE to account for the 702(b) portion of the sample.
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, Salmon, Tilapia	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 (1/2 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.). These sample sizes already include the 702(b) reserve for domestic crabmeat/crawfish. For units larger than 3 lb. only: 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. These sample sizes already include the 702(b) reserve for domestic samples. 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 be shipped to the assigned laboratory designated in the current FY Collection Schedule.

PART IV - ANALYTICAL

A. ANALYZING LABORATORIES

Refer to current FY Collection Schedule for laboratory assignments for each district.

For residues requiring both confirmatory and determinative 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:

Denver District Laboratory
ATTN: Sample Custodian
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. #.

Copies of all methods listed below can be obtained from George W. Salem, ORA, ORO, Division of Field Science HFC-141, Phone (301) 827-1031; E-mail: george.salem@fda.hhs.gov.

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

3. Sample Preparation and Methodology

Refer to the current FY Collection Schedule for priority of methods

to be run on each species.

Catfish/*Basa* and other *Pangasius* species

Sample Preparation: Homogenize muscle (i.e. no skin) according to the method. For domestic samples retain 225 g as the 702(b) portion from each of the 12 fish samples in the lot.

Malachite Green

LIB 4363 Quantitative and Confirmatory Analyses of Malachite Green and Leucomalachite Green Residues in Fish and Shrimp, November 2005

Fluoroquinolones

Determinative procedure:
"Concurrent Determination of Four Fluoroquinolones; Ciprofloxacin, Enrofloxacin, Sarafloxacin and Difloxacin in Atlantic Salmon Tissue by LC with Fluorescence Detection," Revision: October 24, 2003.

Note: The determinative method was developed and validated for four Fluoroquinolones in salmon, catfish, and shrimp. Salmon was selected as the test species for the inter-laboratory non-INAD method trial.

Confirmatory procedure:
LIB 4108 Confirmation of Fluoroquinolones in Catfish Tissue by Electrospray LC/MS, August 1997.

Confirmation: For sample residues at 5 ppb or greater, perform a confirmation of identity. Contact the Denver District Laboratory for confirmation of identity testing.

Quinolones: Oxolinic Acid and Flumequine

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.

Confirmation Procedure: (Using extract from determinative procedure)
"Confirmation of Flumequine, Nalidixic, Oxolinic, and Piromidic acid in Catfish Tissue by GC/MS" by S.B. Turnipseed, A.P. Pfenning, J.E. Roybal, H.S. Rupp, C.C. Walker, S.M. Plakas, and A.R. Long.

Confirmation:
For sample residues at 20 ppb or higher, contact the Denver District Laboratory for confirmation of identity testing.

Crabmeat/Crawfish

All crabmeat samples are to be analyzed on an individual sub basis. The confirmation of chloramphenicol in a single subsample is sufficient to establish presence of CAP in a sample. The lab is to continue analyzing individual subsamples until chloramphenicol 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. It is suggested that laboratories homogenize sample by grinding with dry ice (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). 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.

LIB 4306 Determination of Chloramphenicol Residues in Shrimp and Crab Tissues by Electrospray Triple Quadrupole LC/MS/MS, June 2003.

LIB 4302 LC/MS/MS Analysis of Chloramphenicol in Crab Meat, April 2003.

LIB 4303 LC/MS/MS Analyses of Chloramphenicol in Crawfish Meat, April 2003.

Salmon

Sample Preparation: The sample must be prepared by the appropriate procedure, as outlined in Pesticide Analytical Manual, Volume I, (PAM), 3rd. Ed. (1994, Updated October, 1999), Section 102, Table 102-a. For domestic samples retain 225 g as the 702(b) portion from each of 12 fish sampled in the lot.

Ivermectin

Determinative procedure:
"LC Fluorescence Determination of Ivermectin in Salmon Muscle Tissue," Revision: December 31, 2002.

Confirmatory procedure:
LIB 4158 Confirmation of Ivermectin Residues in Food Matrices with Negative Ion Atmospheric Pressure Chemical Ionization LC/MS, April 1999.

Malachite Green

LIB 4363 Quantitative and Confirmatory Analyses of Malachite Green and Leucomalachite Green Residues in Fish and Shrimp, November 2005

Quinolones: Flumequine

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.

Confirmatory procedure: (Using extract from determinative procedure)
"Confirmation of Flumequine, Nalidixic, Oxolinic, and Piromidic acid in Catfish Tissue by GC/MS" by S.B. Turnipseed, A.P. Pfenning, J.E. Roybal, H.S. Rupp, C.C. Walker, S.M. Plakas, and A.R. Long (submitted to CVM 9/30/94).

Confirmation:
For sample residues at 20 ppb or higher, contact the Denver District Laboratory for confirmation of identity testing.

Oxolinic Acid

Determinative procedure:
"Determination of Oxolinic Acid Residues in Salmon Muscle by Liquid Chromatography with Fluorescence Detection" J. AOAC Int. 74(4) 1991 p. 608-611.

Confirmation method:
"Confirmation of Incurred Residues of Flumequine, Nalidixic, Oxolinic, and Piromidic Acids in Shrimp and Salmon" LIB-4039, July 1996.

Confirmation:
For sample residues at 10 ppb or higher, contact the Denver District Laboratory for confirmation of identity testing.

Shrimp

For CAP and Nitrofurans:
All shrimp samples are to be analyzed 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 (ref 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). 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 all other residues:
Sample Preparation: 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 (ref 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). 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.

Nitrofurans

"Detection of Nitrofuran Metabolites in Shrimp, Reported April 01, 2004" (LIB Pending)

Chloramphenicol

LIB 4306 Determination of Chloramphenicol Residues in Shrimp and Crab Tissues by Electrospray Triple Quadrupole LC/MS/MS, June 2003.

LC/MS/MS Analysis of Chloramphenicol in Shrimp:
Laboratory Information Bulletin No. 4290, September 2002.

Fluoroquinolones

Determinative procedure:
"Concurrent Determination of Four Fluoroquinolones; Ciprofloxacin, Enrofloxacin, Sarafloxacin and Difloxacin in Atlantic Salmon Tissue by LC with Fluorescence Detection," Revision: October 24, 2003.

Note: The determinative method was developed and validated for four Fluoroquinolones in salmon, catfish, and shrimp. Salmon was selected as the test species for the inter-laboratory non-INAD method trial.

Confirmatory procedure:
LIB 4108 Confirmation of Fluoroquinolones in Catfish Tissue by Electrospray LC/MS, August 1997.

Confirmation: For sample residues at 5 ppb or greater, perform a confirmation of identity. Contact the Denver District Laboratory for confirmation of identity testing.

Quinolones: Oxolinic Acid and Flumequine

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."

"Oxolinic Acid and Flumequine Residues in Shrimp by HPLC with Fluorescence Detection" LIB #4336, December 2004.

Confirmation Method: (Using extract from determinative procedure)
"Confirmation of Flumequine, Nalidixic, Oxolinic, and Piromidic acid in Catfish Tissue by GC/MS" by S.B. Turnipseed, A.P. Pfenning, J.E. Roybal, H.S. Rupp, C.C. Walker, S.M. Plakas, and A.R. Long.

Confirmation:
For sample residues at 20 ppb or higher, contact the Denver District Laboratory for confirmation of identity testing.

***Tilapia**

Methyltestosterone

"LC-MS/MS Determinative and Confirmatory Assays of 17α-Methyltestosterone in Fish," by Pak-Sin Chu and Mayda Lopez, November 28, 2005.

Malachite Green

LIB 4363 Quantitative and Confirmatory Analyses of Malachite Green and Leucomalachite Green Residues in Fish and Shrimp, November 2005

Fluoroquinolones

Determinative procedure:
"Concurrent Determination of Four Fluoroquinolones; Ciprofloxacin, Enrofloxacin, Sarafloxacin and Difloxacin in Atlantic Salmon Tissue by LC with Fluorescence Detection," Revision: October 24, 2003.

Note: The determinative method was developed and validated for four Fluoroquinolones in salmon, catfish, and shrimp. Salmon was selected as the test species for the inter-laboratory non-INAD method trial.

Confirmatory procedure:
LIB 4108 Confirmation of Fluoroquinolones in Catfish Tissue by Electrospray LC/MS, August 1997.

Confirmation: For sample residues at 5 ppb or greater, perform a confirmation of identity. Contact the Denver District Laboratory for confirmation of identity testing.*

C. LEVELS of CONFIRMATION

The following values are the current test levels supported by CVM as sufficient for detecting presence of each residue.

Species	Residue	Confirmation Level (ppb)
Catfish and *Basa* and other *Pangasius* Species	Malachite Green	#
	Fluoroquinolones	#
	Quinolones (Oxolinic Acid, Flumequine)	#
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.
- The presence and confirmation (if applicable) of the residue found is in any sample 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.

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 and Poultry as a guide in conducting on-farm investigations, hauler, and/or investigations at the veterinarian's office.

Feed Mill Follow-up:

- Follow-up at the feed mill if the producer uses commercial feeds
- Use Compliance Program 7371.004 as a reference.

CVM General and Regulatory Contact: Fran Pell, (301) 827-0188,

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

Program Contact:

*Robyn R. Jones (Ms. Jones will be on detail outside CPB during most of FY 07; Ms. Wade is alternate)	CFSAN, Office of Compliance, Division of Field Programs, Compliance Programs Branch, HFS-636, (301) 436-2575, Fax (301) 436-2657, robyn.jones@fda.hhs.gov*
Andrea Wade	(301) 436-2079, Fax (301) 436-2657 andrea.wade@fda.hhs.gov

Center Regulatory Contacts:

*Import Regulatory Giselle Jordan	CFSAN, Office of Compliance, Division of Enforcement, Imports Branch HFS-606, (301) 436-1576, giselle.jordan@fda.hhs.gov*
*Domestic Regulatory Mildred Benjamin (Team Leader)	CFSAN, Office of Compliance, Division of Enforcement, Domestic Branch HFS-607, (301) 436-1424, mildred.benjamin@fda.hhs.gov
Priya Rathnam	CFSAN, Office of Compliance, Division of Enforcement, Domestic Branch HFS-607, (301) 436-2078, priya.rathnam@fda.hhs.gov
Crystal McKenna	CFSAN, Office of Compliance, Division of Enforcement, Domestic Branch HFS-607, (703) 719-5718, crystal.mckenna@fda.hhs.gov
Frank Sikorsky	CFSAN, Office of Compliance, Division of Enforcement, Domestic Branch HFS-607, (301) 436-1623, frank.sikorsky@fda.hhs.gov*

Scientific Contact:

*Barbara Montwill	CFSAN, Office of Seafood, DPEPOS, 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, (301) 827-0188, frances.pell@fda.hhs.gov

ORA Contacts:

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 George Salem	ORO, DFS, HFC-141, (301) 827-1031 gsalem@fda.hhs.gov

Method Analysis Contacts:

Chloramphenicol Allen Pfenning Jose Roybal	Animal Drug Research Center (ADRC) Denver, CO, (303) 236-3074/3 apfennin@fda.hhs.gov jroybal@fda.hhs.gov
*Fluoroquinolones Jose Roybal	Animal Drug Research Center (ADRC) Denver, CO, (303) 236-3073/2 jroybal@fda.hhs.gov*
*Ivermectin Heidi Rupp	Pacific Regional Laboratory, NW Seattle, WA, (425) 402-3170 hrupp@fda.hhs.gov*
Malachite Green Jose Roybal Sherri Turnipseed	Animal Drug Research Center (ADRC) Denver, CO, (303) 236-3073/2 jroybal@fda.hhs.gov sturnips@fda.hhs.gov
Quinolones, Oxolinic Acid Allen Pfenning Sherri Turnipseed	Animal Drug Research Center (ADRC) Denver, CO, (303) 236-3074/2 apfennin@fda.hhs.gov sturnips@fda.hhs.gov

PART VII - CENTER RESPONSIBILITIES

Program Evaluation

The Office of Seafood has the responsibility to prepare periodic formal evaluations of this compliance program. %