

MATRICES FOR TRACKING MAJOR AQUACULTURE DRUG APPROVAL DEVELOPMENT

ORAL OXYTETRACYCLINE (TERRAMYCIN® 100 FOR FISH) MATRIX 1 OF 4: MATRIX RESEARCH AND DEVELOPMENT PLAN AND DRAFT LABEL CLAIM FOR SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION (NADA) APPROVALS FOR THE CONTROL OF MORTALITY IN

1. Freshwater-reared salmonids due to systemic coldwater disease
2. Steelhead trout due to systemic columnaris disease

DEVELOPED UNDER THE FEDERAL-STATE
AQUACULTURE DRUG APPROVAL PARTNERSHIP
PROJECT, A PROJECT OF THE INTERNATIONAL
ASSOCIATION OF FISH AND WILDLIFE AGENCIES

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<http://aq.ansc.purdue.edu/aquanic/jsa/aquadrugs/index.htm>

ORAL OXYTETRACYCLINE MATRIX 1 OF 4, VERSION 1
(January 6, 2006)

ABBREVIATIONS, ACRONYMS, & CONTACT INFORMATION FOR ENTITIES IN TABLE

AADAPP	Aquatic Animal Drug Approval Partnership Program—Dr. David Erdahl, U.S. Fish and Wildlife Service, 4050 Bridger Canyon Road, Bozeman, Montana 59715; Phone: 406-994-9904; Fax: 406-582-0242; E-mail: Dave_Erdahl@fws.gov
AOI	All Other Information Technical Section, not included in any of the other sections, that is pertinent to an evaluation of effectiveness or safety [21 CFR § 514.1(b)(8)(iv)]
CVM	Aquaculture Drugs Team (HFV-131), Division of Therapeutic Drugs for Food Animals, Office of New Animal Drug Evaluations, Center for Veterinary Medicine, U.S. Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855; Dr. Donald Prater; Phone: 301-827-7567; E-mail: DPrater@CVM.FDA.GOV ; Dr. Susan Storey; Phone: 301-827-7581; Sstorey@CVM.FDA.GOV
Efficacy	Effectiveness Technical Section includes pivotal & supportive studies that show whether or not a drug is effective for its intended use [21 CFR § 514.1(b)(8)(i)]
FOI	Final Freedom of Information summary generated by CVM based on draft FOIs developed by researchers for each study [21 CFR § 514.11(e)(2)(ii)]
INAD	Investigational New Animal Drug exemption [21 CFR 511]
Label	Labeling Technical Section includes labeling and package inserts [21 CFR § 514.1(b)(3)]
NADA	New Animal Drug Application [21 CFR 514]
NADA Coordinator	Rosalie (Roz) Schnick, National Coordinator for Aquaculture New Animal Drug Applications, Michigan State University, 3039 Edgewater Lane, La Crosse, Wisconsin 54603-1088; Phone: 608-781-2205; Fax: 608-783-3507; E-mail: RozSchnick@centurytel.net
PHIBRO	Sponsor of oral oxytetracycline (Terramycin® 100 for Fish): Paul F. Duquette, Director, Global Regulatory Affairs, Phibro Animal Health, 65 Challenger Road, 3 rd floor, Ridgefield Park, NJ 07660; Phone: 201-329-7375; E-mail: paul.duquette@pahc.com ;
Product Chemistry	Product Chemistry Technical Section includes chemistry, manufacturing, and controls [21 CFR § 514.1(b)(4-6)]
PMF	Public Master File can contain safety and efficacy data and information generated with public funds (Guidance Document #57)
Toxicology	Part of Human Food Safety Technical Section, toxicological testing includes genetic toxicity tests and mammalian safety studies (e.g., acute, subchronic) (Guidance Document #3)
UMESC	Upper Midwest Environmental Sciences Center—Dr. William Gingerich, 2630 Fanta Reed Road, La Crosse, Wisconsin 54603; Phone: 608-783-6451; Fax: 608-783-6066; E-mail: bill_gingerich@usgs.gov

KEY TO COLOR CODING

COLOR	STATUS
	No current plans and/or funds
	In progress or planned; funded
	Submitted to CVM
	Accepted by CVM

INITIAL SUPPLEMENTAL NADA—OXYTETRACYCLINE (ORAL) = For the control of mortality in

1. Freshwater-reared salmonids due to systemic coldwater disease associated with *Flavobacterium psychrophilum*
2. Steelhead trout due to systemic columnaris disease associated with *Flavobacterium columnare* (*Flexibacter columnaris*)

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Product Chemistry (all fish)	PHIBRO (INAD #11-368)—Product chemistry package—previously accepted	None
Product Chemistry (all fish)	PHIBRO (INAD #11-368)—Product chemistry package/change quaternary ammonium salt to dihydrate salt—submitted 9/21/05	None—pending acceptance
Environmental Safety (pond, flow-through, & recirculating systems)	PHIBRO (INAD #11-368) & others—Environmental assessment—previously accepted	None
Environmental Safety (pond, flow-through, & recirculating systems/all finfish)	UMESC (INAD #11-366 & PMF #5646)—Environmental assessment/all finfish—CVM commented on EA 6/3/05 (no studies required)—revision in progress	None—pending acceptance
Human Food Safety—Toxicology	PHIBRO (INAD #11-368) & others—Toxicology—previously accepted	None
Human Food Safety—Residue Chemistry (salmonids & catfish)	PHIBRO (INAD #11-368) & others—Residue depletion studies in salmonids and catfish—previously accepted	None
Human Food Safety—Residue Chemistry (rainbow trout)	UMESC (INAD #11-366 & PMF #5646)—Bridged official microbial inhibition assay with HPLC method/rainbow trout—accepted 9/11/97	None
Human Food Safety—Residue Chemistry (all finfish)	UMESC (INAD #11-366 & PMF #5646)—Liquid chromatographic determination/six fish species fillets—accepted 12/8/00 & follow-up response 9/9/02	None
Human Food Safety—Residue Chemistry (all finfish)	UMESC (INAD #11-366 & PMF #5646)—Bridged official microbial inhibition assay with robust HPLC method/all finfish—accepted 12/8/00 & follow-up response 9/9/02	None
Human Food Safety—Residue Chemistry (all freshwater-reared salmonids)	UMESC (INAD #11-366 & PMF #5646)—Marker residue depletion studies for all juvenile freshwater-reared salmonids below 9° C—accepted 9/9/99	None
Human Food Safety—Residue Chemistry (all salmonids)	UMESC (INAD #11-366 & PMF #5646)—Extrapolated withdrawal times for all sizes of salmonids—accepted 5/17/02	None
Human Food Safety—Microbial Food Safety (all finfish)	UMESC (INAD #11-366 & PMF #5646)—Microbial food safety/all finfish—submitted 10/30/02; CVM requested microbial food safety assessment 4/1/03	None—see below
Human Food Safety—Microbiological toxicology of residues (all finfish)	PHIBRO (INAD #11-368), UMESC, & NADA Coordinator—Microbiological toxicology of residues—Guideline # 159/all finfish—Paper argument to add to other NADAs (8-804 & 95-143) for aquaculture NADAs—in progress	None—pending acceptance
Human Food Safety—Microbial Food Safety (freshwater-reared salmonids)	PHIBRO (INAD #11-368) & AADAPP—Microbial food safety—Guideline #152/ freshwater-reared salmonids—Hazard Characterization in progress	None—pending acceptance
Target Animal Safety (catfish and salmonids)	PHIBRO (INAD #11-368) & others—Target animal safety/salmonids and catfish—previously accepted	None

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Efficacy (original NADA efficacy/catfish & salmonids)	PHIBRO (INAD #11-368)—Efficacy/bacterial hemorrhagic septicemia and pseudomonas disease/catfish and ulcer disease, furunculosis, bacterial hemorrhagic septicemia, and pseudomonas disease/salmonids—previously accepted	None
Efficacy (all label claims/all finfish)	UMESC (INAD #11-366 & PMF #5646)—Developed analytical method to detect oxytetracycline in feed in support of all INAD testing—accepted 7/29/98	None
Efficacy (systemic coldwater disease/salmonids)	UMESC (INAD #11-366 & PMF #5646)—Efficacy/systemic coldwater disease/all freshwater-reared salmonids—accepted Data Call-in as supportive 2/1/00	None
Efficacy (systemic coldwater disease/salmonids)	AADAPP (INAD #9006 & 9332)—Efficacy/coldwater disease/all freshwater-reared salmonids—accepted as pivotal 11/23/01	None
Efficacy (systemic columnaris disease/salmonids)	UMESC (INAD #11-366 & PMF #5646)—Efficacy/systemic columnaris disease/all freshwater-reared salmonids—accepted Data Call-in as supporting 2/1/00	None
Efficacy (systemic columnaris disease/steelhead trout)	AADAPP (INAD #9006 & 9332)—Efficacy/systemic columnaris disease/steelhead trout—accepted as pivotal 11/14/00	None
Efficacy (systemic columnaris disease/salmonids)	AADAPP (INAD #9006 & 9332)—Efficacy/systemic columnaris disease/coho salmon or Chinook salmon—planned	None—pending acceptance
Label (change in salt)	PHIBRO (INAD #11-368)—Label/change in salt—in progress	None—pending acceptance
Label (systemic coldwater disease/salmonids & systemic columnaris disease/steelhead trout)	PHIBRO (INAD #11-368) & NADA Coordinator—Label/systemic coldwater disease/salmonids & systemic columnaris disease/steelhead trout—in progress	None—pending acceptance
FOI (systemic coldwater disease/salmonids & systemic columnaris disease/steelhead trout)	CVM—FOI/systemic coldwater disease/salmonids & systemic columnaris disease/steelhead trout—in progress with PHIBRO, UMESC, & AADAPP input	None—pending acceptance
AOI (systemic coldwater disease/salmonids & systemic columnaris disease/steelhead trout)	PHIBRO (INAD #11-368) & NADA Coordinator—AOI/systemic coldwater disease/salmonids & systemic columnaris disease/steelhead trout—planned before administrative NADA submission	None—pending acceptance
NADA Package (systemic coldwater disease/salmonids & systemic columnaris disease/steelhead trout)	PHIBRO (INAD #11-368) & NADA Coordinator—NADA package/systemic coldwater disease/salmonids & systemic columnaris disease/steelhead trout—in progress	None—pending acceptance

DRAFT LABEL CLAIMS FOR TERRAMYCIN® 100 FOR FISH

LABEL CLAIM #1: FOR FRESHWATER-REARED SALMONIDS

INDICATIONS: For the control of mortality in freshwater-reared salmonids due to systemic coldwater disease associated with *Flavobacterium psychrophilum*

DIRECTIONS FOR USE: Apply Terramycin® 100 for Fish in medicated feed at a dose of 3.7 grams oxytetracycline per 100 pounds of fish per day for ten consecutive days.

LABEL CLAIM #2: FOR STEELHEAD TROUT (*ONCORHYNCHUS MYKISS*)

INDICATIONS: For the control of mortality in steelhead trout due to systemic columnaris disease associated with *Flavobacterium columnare* (*Flexibacter columnaris*)

DIRECTIONS FOR USE: Apply Terramycin® 100 for Fish in medicated feed at a dose of 3.75 grams oxytetracycline per 100 pounds of fish per day for ten consecutive days.

**MATRICES FOR TRACKING MAJOR AQUACULTURE
DRUG APPROVAL DEVELOPMENT**

**ORAL OXYTETRACYCLINE (TERRAMYCIN® 100 FOR
FISH) MATRIX 2 OF 4: MATRIX RESEARCH AND
DEVELOPMENT PLAN AND DRAFT LABEL CLAIM
FOR SUPPLEMENTAL NEW ANIMAL DRUG
APPLICATION (NADA) APPROVAL FOR THE
CONTROL OF MORTALITY IN**

**1. Freshwater-reared finfish due to systemic
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**ORAL OXYTETRACYCLINE MATRIX 2 OF 4, VERSION 1
(January 6, 2006)**

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Label	Labeling Technical Section includes labeling and package inserts [21 CFR § 514.1(b)(3)]
NADA	New Animal Drug Application [21 CFR 514]
NADA Coordinator	Rosalie (Roz) Schnick, National Coordinator for Aquaculture New Animal Drug Applications, Michigan State University, 3039 Edgewater Lane, La Crosse, Wisconsin 54603-1088; Phone: 608-781-2205; Fax: 608-783-3507; E-mail: RozSchnick@centurytel.net
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	In progress or planned; funded
	Submitted to CVM
	Accepted by CVM

INITIAL SUPPLEMENTAL NADA—OXYTETRACYCLINE (ORAL) = For the control of mortality in

1. Freshwater-reared finfish due to systemic columnaris disease associated with *Flavobacterium columnare* (*Flexibacter columnaris*)

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Product Chemistry (all fish)	PHIBRO (INAD #11-368)—Product chemistry package—previously accepted	None
Product Chemistry (all fish)	PHIBRO (INAD #11-368)—Product chemistry package/change quaternary ammonium salt to dihydrate salt—submitted 9/21/05	None—pending acceptance
Environmental Safety (pond, flow-through, & recirculating systems)	PHIBRO (INAD #11-368) & others—Environmental assessment—previously accepted	None
Environmental Safety (pond, flow-through, & recirculating systems/all finfish)	UMESC (INAD #11-366 & PMF #5646)—Environmental assessment/all finfish—CVM commented on EA 6/3/05 (no studies required)—revision in progress	None—pending acceptance
Human Food Safety—Toxicology	PHIBRO (INAD #11-368) & others—Toxicology—previously accepted	None
Human Food Safety—Residue Chemistry (salmonids & catfish)	PHIBRO (INAD #11-368) & others—Residue depletion studies in salmonids and catfish—previously accepted	None
Human Food Safety—Residue Chemistry (rainbow trout)	UMESC (INAD #11-366 & PMF #5646)—Bridged official microbial inhibition assay with HPLC method/rainbow trout—accepted 9/11/97	None
Human Food Safety—Residue Chemistry (all finfish)	UMESC (INAD #11-366 & PMF #5646)—Liquid chromatographic determination/six fish species filets—accepted 12/8/00 & follow-up response 9/9/02	None
Human Food Safety—Residue Chemistry (all finfish)	UMESC (INAD #11-366 & PMF #5646)—Bridged official microbial inhibition assay with robust HPLC method/all finfish—accepted 12/8/00 & follow-up response 9/9/02	None
Human Food Safety—Residue Chemistry (all freshwater-reared salmonids)	UMESC (INAD #11-366 & PMF #5646)—Marker residue depletion studies for all juvenile freshwater-reared salmonids below 9° C—accepted 9/9/99	None
Human Food Safety—Residue Chemistry (all salmonids)	UMESC (INAD #11-366 & PMF #5646)—Extrapolated withdrawal times for all sizes of salmonids—accepted 5/17/02	None
Human Food Safety—Microbial Food Safety (all finfish)	UMESC (INAD #11-366 & PMF #5646)—Microbial food safety/all finfish—submitted 10/30/02; CVM requested microbial food safety assessment 4/1/03	None—see below
Human Food Safety—Microbiological toxicology of residues (all finfish)	PHIBRO (INAD #11-368), UMESC, & NADA Coordinator—Microbiological toxicology of residues—Guideline # 159/all finfish—Paper argument to add to other NADAs (8-804 & 95-143) for aquaculture NADAs—in progress	None—pending acceptance
Human Food Safety—Microbial Food Safety (coolwater and warmwater finfish)	PHIBRO (INAD #11-368) & AADAPP—Microbial food safety—Guideline #152/coolwater and warmwater finfish—Qualitative Risk Assessment—planned in the future when efficacy data have been accepted	None—pending acceptance
Target Animal Safety (catfish and salmonids)	PHIBRO (INAD #11-368) & others—Target animal safety/salmonids and catfish—previously accepted	None

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Efficacy (original NADA efficacy/catfish & salmonids)	PHIBRO (INAD #11-368)—Efficacy/bacterial hemorrhagic septicemia and pseudomonas disease/catfish and ulcer disease, furunculosis, bacterial hemorrhagic septicemia, and pseudomonas disease/salmonids—previously accepted	None
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Efficacy (systemic columnaris disease/salmonids)	UMESC (INAD #11-366 & PMF #5646)—Efficacy/systemic columnaris disease/all freshwater-reared salmonids—accepted Data Call-in as supporting 2/1/00	None
Efficacy (systemic columnaris disease/steelhead trout)	AADAPP (INAD #9006 & 9332)—Efficacy/systemic columnaris disease/steelhead trout—accepted as pivotal 11/14/00	None
Efficacy (systemic columnaris disease/salmonids)	AADAPP (INAD #9006 & 9332)—Efficacy/systemic columnaris disease/coho salmon or Chinook salmon—planned	None—pending acceptance
Efficacy (systemic columnaris disease/coolwater & warmwater fish)	No entity identified—Pivotal efficacy/systemic columnaris disease/coolwater & warmwater fish—not planned	Needs to be planned
Label (change in salt)	PHIBRO (INAD #11-368)—Label/change in salt—in progress	None—pending acceptance
Label (systemic columnaris disease/freshwater-reared finfish)	PHIBRO (INAD #11-368) & NADA Coordinator—Label/systemic columnaris disease/freshwater-reared finfish—i planned if efficacy accepted	None—pending acceptance
FOI (systemic columnaris disease/freshwater-reared finfish)	CVM—FOI/systemic columnaris disease/freshwater-reared finfish—planned if efficacy accepted	None—pending acceptance
AOI (systemic columnaris disease/freshwater-reared finfish)	PHIBRO (INAD #11-368) & NADA Coordinator—AOI/systemic columnaris disease/freshwater-reared finfish—planned if efficacy accepted	None—pending acceptance
NADA Package (systemic columnaris disease/freshwater-reared finfish)	PHIBRO (INAD #11-368) & NADA Coordinator—NADA package/systemic columnaris disease/freshwater-reared finfish—planned if efficacy accepted	None—pending acceptance

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MATRICES FOR TRACKING MAJOR AQUACULTURE DRUG APPROVAL DEVELOPMENT

ORAL OXYTETRACYCLINE (TERRAMYCIN® 100 FOR FISH) MATRIX 3 OF 4: MATRIX RESEARCH AND DEVELOPMENT PLAN AND DRAFT LABEL CLAIM FOR SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION (NADA) APPROVAL FOR THE CONTROL OF MORTALITY IN

1. Freshwater-reared finfish due to motile aeromonad septicemia associated with *Aeromonas hydrophila*

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ORAL OXYTETRACYCLINE MATRIX 3 OF 4, VERSION 1
(January 6, 2006)

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SUPPLEMENTAL NADA—OXYTETRACYCLINE (ORAL)=For the control of mortality in

1. Freshwater-reared finfish due to motile aeromonad septicemia associated with *Aeromonas hydrophila*

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Product Chemistry (all fish)	PHIBRO (INAD #11-368)—Product chemistry package—previously accepted	None
Product Chemistry (all fish)	PHIBRO (INAD #11-368)—Product chemistry package/change quaternary ammonium salt to dihydrate salt—submitted 9/21/05	None—pending acceptance
Environmental Safety (pond, flow-through, & recirculating systems)	PHIBRO (INAD #11-368) & others—Environmental assessment—previously accepted	None
Environmental Safety (pond, flow-through, & recirculating systems/all finfish)	UMESC (INAD #11-366 & PMF #5646)—Environmental assessment/all finfish—CVM commented on EA 6/3/05 (no studies required)—revision in progress	None—pending acceptance
Human Food Safety—Toxicology	PHIBRO (INAD #11-368) & others—Toxicology—previously accepted	None
Human Food Safety—Residue Chemistry (salmonids & catfish)	PHIBRO (INAD #11-368) & others—Residue depletion studies in salmonids and catfish—previously accepted	None
Human Food Safety—Residue Chemistry (rainbow trout)	UMESC (INAD #11-366 & PMF #5646)—Bridged official microbial inhibition assay with HPLC method/rainbow trout—accepted 9/11/97	None
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Target Animal Safety (catfish and salmonids)	PHIBRO (INAD #11-368) & others—Target animal safety/salmonids and catfish—previously accepted	None

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Efficacy (original NADA efficacy/catfish & salmonids)	PHIBRO (INAD #11-368)—Efficacy/bacterial hemorrhagic septicemia and pseudomonas disease/catfish and ulcer disease, furunculosis, bacterial hemorrhagic septicemia, and pseudomonas disease/salmonids—previously accepted	None
Efficacy (all label claims/all finfish)	UMESC (INAD #11-366 & PMF #5646)—Developed analytical method to detect oxytetracycline in feed in support of all INAD testing—accepted 7/29/98	None
Efficacy (<i>Aeromonas</i> sp./northern pike)	UMESC (PMF #5646)—Efficacy/ <i>Aeromonas</i> sp./northern pike—accepted Data Call-in as supportive 2/1/00	None
Efficacy (motile aeromonad septicemia/freshwater-reared finfish)	No entity identified—Pivotal efficacy/motile aeromonad septicemia/freshwater-reared finfish—not planned	Needs to be planned
Label (change in salt)	PHIBRO (INAD #11-368)—Label/change in salt—in progress	None—pending acceptance
Label (motile aeromonad septicemia/freshwater-reared finfish)	PHIBRO (INAD #11-368) & NADA Coordinator—Label/motile aeromonad septicemia/freshwater-reared finfish—planned if efficacy accepted	None—pending acceptance
FOI (motile aeromonad septicemia/freshwater-reared finfish)	CVM—FOI/motile aeromonad septicemia/freshwater-reared finfish—planned if efficacy accepted	None—pending acceptance
AOI (motile aeromonad septicemia/freshwater-reared finfish)	PHIBRO (INAD #11-368) & NADA Coordinator—AOI/motile aeromonad septicemia/freshwater-reared finfish—planned if efficacy accepted	None—pending acceptance
NADA Package (motile aeromonad septicemia/freshwater-reared finfish)	PHIBRO (INAD #11-368) & NADA Coordinator—NADA package/motile aeromonad septicemia/freshwater-reared finfish—planned if efficacy accepted	None—pending acceptance

DRAFT LABEL CLAIM FOR TERRAMYCIN® 100 FOR FISH

LABEL CLAIM #1: FOR FRESHWATER-REARED FINFISH

INDICATIONS: For the control of mortality in freshwater-reared finfish due to motile aeromonad septicemia associated with *Aeromonas hydrophila*

DIRECTIONS FOR USE: Apply Terramycin® 100 for Fish in medicated feed at a dose of 3.75 grams oxytetracycline per 100 pounds of fish per day for ten consecutive days.

MATRICES FOR TRACKING MAJOR AQUACULTURE DRUG APPROVAL DEVELOPMENT

ORAL OXYTETRACYCLINE (TERRAMYCIN® 100 FOR FISH) MATRIX 4 OF 4: MATRIX RESEARCH AND DEVELOPMENT PLAN AND DRAFT LABEL CLAIM FOR SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION (NADA) APPROVAL FOR THE CONTROL OF MORTALITY IN

1. Penaeid shrimp due to necrotizing hepatopancreatitis

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ORAL OXYTETRACYCLINE MATRIX 4 OF 4, VERSION 1
(January 6, 2006)

ABBREVIATIONS, ACRONYMS, & CONTACT INFORMATION FOR ENTITIES IN TABLE

AOI	All Other Information Technical Section, not included in any of the other sections, that is pertinent to an evaluation of effectiveness or safety [21 CFR § 514.1(b)(8)(iv)]
CVM	Aquaculture Drugs Team (HFV-131), Division of Therapeutic Drugs for Food Animals, Office of New Animal Drug Evaluations, Center for Veterinary Medicine, U.S. Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855; Dr. Donald Prater; Phone: 301-827-7567; E-mail: DPrater@CVM.FDA.GOV ; Dr. Susan Storey; Phone: 301-827-7581; Sstorey@CVM.FDA.GOV
Efficacy	Effectiveness Technical Section includes pivotal & supportive studies that show whether or not a drug is effective for its intended use [21 CFR § 514.1(b)(8)(i)]
FOI	Final Freedom of Information summary generated by CVM based on draft FOIs developed by researchers for each study [21 CFR § 514.11(e)(2)(ii)]
INAD	Investigational New Animal Drug exemption [21 CFR 511]
Label	Labeling Technical Section includes labeling and package inserts [21 CFR § 514.1(b)(3)]
NADA	New Animal Drug Application [21 CFR 514]
NADA Coordinator	Rosalie (Roz) Schnick, National Coordinator for Aquaculture New Animal Drug Applications, Michigan State University, 3039 Edgewater Lane, La Crosse, Wisconsin 54603-1088; Phone: 608-781-2205; Fax: 608-783-3507; E-mail: RozSchnick@centurytel.net
PHIBRO	Sponsor of oral oxytetracycline (Terramycin® 100 for Fish): Paul F. Duquette, Director, Global Regulatory Affairs, Phibro Animal Health, 65 Challenger Road, 3 rd floor, Ridgefield Park, NJ 07660; Phone: 201-329-7375; E-mail: paul.duquette@pahc.com ;
Product Chemistry	Product Chemistry Technical Section includes chemistry, manufacturing, and controls [21 CFR § 514.1(b)(4-6)]
PMF	Public Master File can contain safety and efficacy data and information generated with public funds (Guidance Document #57)
Toxicology	Part of Human Food Safety Technical Section, toxicological testing includes genetic toxicity tests and mammalian safety studies (e.g., acute, sub chronic) (Guidance Document #3)
UAZ	University of Arizona; Rodney Williams, Department of Veterinary Sciences, Tucson, AZ 85721; Phone: 602-293-3502; Fax: 602-293-3502; E-mail: rodneyw@Ag.arizona.edu
UMESC	Upper Midwest Environmental Sciences Center—Dr. William Gingerich, 2630 Fanta Reed Road, La Crosse, Wisconsin 54603; Phone: 608-783-6451; Fax: 608-783-6066; E-mail: bill_gingerich@usgs.gov

KEY TO COLOR CODING

COLOR	STATUS
	No current plans and/or funds
	In progress or planned; funded
	Submitted to CVM
	Accepted by CVM

**SUPPLEMENTAL NADA—OXYTETRACYCLINE (ORAL) = For the control of mortality in
1. Penaeid shrimp due to necrotizing hepatopancreatitis**

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Product Chemistry (all fish)	PHIBRO (INAD #11-368)—Product chemistry package—previously accepted	None
Product Chemistry (all fish)	PHIBRO (INAD #11-368)—Product chemistry package/change quaternary ammonium salt to dihydrate salt—submitted 9/21/05	None—pending acceptance
Environmental Safety (pond, flow-through, & recirculating systems)	PHIBRO (INAD #11-368) & others—Environmental assessment—previously accepted	None
Environmental Safety (pond, flow-through, & recirculating systems/all finfish)	UMESC (INAD #11-366 & PMF #5646)—Environmental assessment/all finfish—CVM commented on EA 6/3/05 (no studies required)—revision in progress	None—pending acceptance
Environmental Safety (pond, flow-through, & recirculating systems/penaeid shrimp)	UAZ (INAD #8069)—Environmental assessment additional data/penaeid shrimp—in progress	None—pending acceptance
Human Food Safety—Toxicology (all finfish & lobster)	PHIBRO (INAD #11-368) & others—Toxicology/all finfish & lobster—previously accepted	None
Human Food Safety—Toxicology (penaeid shrimp)	PHIBRO (INAD #11-368)—Mammalian toxicology—needs to provide proprietary data to derive ADI for penaeid shrimp	None—pending acceptance
Human Food Safety—Residue Chemistry (penaeid shrimp)	UAZ (INAD #8069)—Residue Chemistry/penaeid shrimp—accepted 11/4/99	None
Human Food Safety—Microbiological toxicology of residues (penaeid shrimp)	PHIBRO (INAD #11-368) & UAZ—Microbiological toxicology of residues—Guideline # 159/penaeid shrimp—Paper argument to add to other NADAs (8-804 & 95-143) for aquaculture NADAs—in progress	None—pending acceptance
Human Food Safety—Microbial Food Safety (penaeid shrimp)	PHIBRO (INAD #11-368) & UAZ—Microbial food safety—Guideline #152/ freshwater-reared salmonids—Qualitative Risk Assessment—in progress	None—pending acceptance
Target Animal Safety (penaeid shrimp)	UAZ (INAD #8069)—Target animal safety/penaeid shrimp—submitted 8/04; CVM responded by requesting more data	None—pending acceptance

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Efficacy (necrotizing hepatopancreatitis/penaeid shrimp)	UAZ (INAD #8069)—Efficacy/necrotizing hepatopancreatitis/penaeid shrimp—accepted 6/28/00	None
Label (change in salt)	PHIBRO (INAD #11-368)—Label/change in salt—in progress	None—pending acceptance
Label ((necrotizing hepatopancreatitis/penaeid shrimp)	PHIBRO (INAD #11-368) & NADA Coordinator—Label/necrotizing hepatopancreatitis/penaeid shrimp—planned	None—pending acceptance
FOI (necrotizing hepatopancreatitis/penaeid shrimp)	CVM—FOI/necrotizing hepatopancreatitis/penaeid shrimp—planned with PHIBRO & UAZ input	None—pending acceptance
AOI (necrotizing hepatopancreatitis/penaeid shrimp)	PHIBRO (INAD #11-368) & NADA Coordinator—AOI/necrotizing hepatopancreatitis/penaeid shrimp—planned	None—pending acceptance
NADA Package (necrotizing hepatopancreatitis/penaeid shrimp)	PHIBRO (INAD #11-368) & NADA Coordinator—NADA package/necrotizing hepatopancreatitis/penaeid shrimp—planned	None—pending acceptance

DRAFT LABEL CLAIM FOR TERRAMYCIN® 100 FOR FISH

LABEL CLAIM #1: FOR PENAID SHRIMP

INDICATIONS: For the control of mortality in penaeid shrimp due to necrotizing hepatopancreatitis

DIRECTIONS FOR USE: Apply Terramycin® 100 for Fish in medicated feed at a dose of 1.5 to 4.5 grams oxytetracycline per kilograms of feed per day for 14 consecutive days.