

AQUACULTURE DRUG APPROVAL DEVELOPMENT STATUS

OXYTETRACYCLINE HYDROCHLORIDE (TERRAMYCIN 343®): RESEARCH AND DEVELOPMENT PLAN AND LABEL CLAIM MATRICES FOR SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION (NADA) APPROVALS

1. [Oxytetracycline hydrochloride \(Terramycin 343®\) NADA approval \(6/13/05\)](#)
2. [Status of Technical Sections that support all supplemental NADA approvals](#)
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4. [Label Claim #2: For the control of mortality in freshwater-reared coolwater and warmwater finfish fry and fingerlings due to bacterial gill disease](#)
5. [Label Claim #3: For the control of mortality in freshwater-reared coolwater and warmwater finfish fry and fingerlings due to systemic columnaris disease](#)

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

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OXYTETRACYCLINE HYDROCHLORIDE (TERRAMYCIN 343®)
(Version 2, March 2008)

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: 240-276-8343; E-mail: Donald.Prater@fda.hhs.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
NRSP-7	National Research Support Project Number 7, CSREES, E-mail: jgb@cornell.edu ; CVM Liaison, E-mail: MOELLER@CVM.FDA.GOV
PFIZER	Sponsor of Terramycin 343®—Mark Subramanyam, Pfizer Animal Health, 7000 Portage Road, RIC-190-43, Kalamazoo, MI 49001-0199; Phone: (269) 833-3388; Fax: (269) 833-2707; E-mail: Mark.Subramanyam@Pfizer.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)
UMESC	Upper Midwest Environmental Sciences Center—Mark Gaikowski, 2630 Fanta Reed Road, La Crosse, Wisconsin 54603; Phone: 608-783-6451; Fax: 608-783-6066; E-mail: MGaikowski@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

OXYTETRACYCLINE HYDROCHLORIDE (TERRAMYCIN 343®)

Oxytetracycline hydrochloride (Terramycin 343®) NADA approval (6/13/05)

Species/Class: All finfish fry and fingerlings

Indications: **For marking of skeletal tissues of finfish fry and fingerlings**

Recommended Dosage: 200-700 mg of oxytetracycline hydrochloride per liter of water for 2-5 hours

OXYTETRACYCLINE HYDROCHLORIDE (TERRAMYCIN 343®)

Status of Technical Sections that support all supplemental NADA approvals

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Product Chemistry	PFIZER (INAD #011-581)—Product chemistry package—previously accepted	None
Environmental Safety (continuous flow-through & pond systems)	NRSP-7 (PMF #5667)—Environmental Safety/environmental assessment/continuous flow-through & pond systems—accepted for marking finfish 7/15/02	None—if covers disease claims
Environmental Safety (continuous flow-through & pond systems)	UMESC (INAD #11-308 & PMF #5646)—Environmental Safety/Environmental risk assessment/all disease claims—in progress	None—if covers disease claims
Environmental Safety (flow-through & ponds)	UMESC (INAD #11-308 & PMF #5646)—Environmental Safety/Methods to remediate effluents/all disease claims—completion report in progress	None—if covers disease claims
Human Food Safety (toxicology)	PFIZER (INAD #011-581)—Human Food Safety/toxicology—previously accepted	None—This Technical Section is complete
Human Food Safety (residue chemistry & microbial safety/all finfish/marketing)	NRSP-7 (PMF #5667)—Human Food Safety/residue data for marking fish—accepted 7/15/02; NRSP-7—microbial safety letter/ marketing finfish—accepted 7/15/02	None—This Technical Section is complete
Human Food Safety (residue chemistry/all finfish/all disease claims)	UMESC (INAD #11-308 & PMF #5646)—Human Food Safety/residue chemistry/bridging of LC method to the official microbial inhibition method & LC method for analysis of finfish tissue/all disease claims—accepted 10/27/04	None
Human Food Safety (residue chemistry/all finfish/all disease claims)	UMESC (INAD #11-308 & PMF #5646)—Human Food Safety/residue chemistry/data/various-sized finfish/all disease claims—completion report in progress	None—pending acceptance—currently using outside funds
Human Food Safety (microbiological effects on bacteria of human health concern /all finfish/all disease claims)	UMESC (INAD #11-308 & PMF #5646)—Human Food Safety/Guidance Document #152: microbiological effects on bacteria of human health concern/all finfish/all disease claims—being planned	None—pending acceptance
Human Food Safety (safety of residues in human food/all finfish/all disease claims)	UMESC (INAD #11-308 & PMF #5646)—Human Food Safety/Guidance Document #159: safety of residues in human food /all finfish/all disease claims—being planned	None—pending acceptance
Target Animal Safety (all finfish)	NRSP-7 (PMF #5667)—Target Animal Safety/all finfish—accepted 7/15/02	None—if covers disease claims
Efficacy (all disease claims)	UMESC (INAD #11-308 & PMF #5646)—Efficacy/HPLC analytical method to verify dose—accepted as suitable as a research method 8/5/04	Needed—standard operating procedure format for complete description

OXYTETRACYCLINE HYDROCHLORIDE (TERRAMYCIN 343®)

LABEL CLAIM #1

SPECIES: COOLWATER AND WARMWATER FRESHWATER-REARED FINFISH FRY AND FINGERLINGS

INDICATIONS: For the control of mortality in coolwater and warmwater freshwater-reared finfish fry and fingerlings due to external columnaris disease associated with *Flavobacterium columnare* (*Flexibacter columnaris*)

DIRECTIONS FOR USE: Apply Terramycin 343® (oxytetracycline hydrochloride) at a concentration of 10 to 40 milligrams per liter [mg/L; equivalent to parts per million (ppm)] in continuous flow water supply of finfish culture units or as a static bath in finfish culture units for 60 minutes daily for three consecutive days.

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Efficacy (external columnaris disease/channel catfish fry & fingerlings)	UMESC (INAD #11-308 & PMF #5646)—Pivotal efficacy/external columnaris disease/channel catfish fry & fingerlings—accepted as supportive 9/14/07	None—pending acceptance—currently using outside funds
Efficacy (external columnaris disease/coolwater & warmwater finfish fry & fingerlings)	UMESC (INAD #11-308 & PMF #5646)—Pivotal efficacy/external columnaris disease/coolwater and warmwater finfish fry & fingerlings—in progress	None—pending acceptance—currently using outside funds
Label	PFIZER (INAD #011-581) & NADA Coordinator—Label—planned in the future after environmental risk assessment, human food safety documents and studies, and efficacy studies are accepted	None—pending acceptance
FOI	CVM—FOI—planned in the future with input from UMESC	None—pending acceptance
AOI	PFIZER (INAD #011-581) & NADA Coordinator—AOI—planned in the future after environmental risk assessment, human food safety documents and studies, and efficacy studies are accepted	None—pending acceptance
NADA Package (disease claims)	PFIZER (INAD #011-581) & NADA Coordinator—NADA package—planned in the future after environmental risk assessment, human food safety documents and studies, and efficacy studies are accepted	None—pending acceptance

OXYTETRACYCLINE HYDROCHLORIDE (TERRAMYCIN 343®)

LABEL CLAIM #2

SPECIES: COOLWATER AND WARMWATER FRESHWATER-REARED FINFISH FRY AND FINGERLINGS

INDICATIONS: For the control of mortality in coolwater and warmwater freshwater-reared finfish fry and fingerlings due to bacterial gill disease associated with *Flavobacterium branchiophilum*

DIRECTIONS FOR USE: Apply Terramycin 343® (oxytetracycline hydrochloride) at a concentration of 10 to 40 milligrams per liter [mg/L; equivalent to parts per million (ppm)] in continuous flow water supply of finfish culture units or as a static bath in finfish culture units for 60 minutes daily for three consecutive days.

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Efficacy (bacterial gill disease/coolwater & warmwater finfish fry & fingerlings)	No entities identified—Efficacy/bacterial gill disease/coolwater & warmwater finfish fry & fingerlings—plans need to be made	Efficacy—need supportive data; may need funding
Label	PFIZER & NADA Coordinator—Label—planned in the future after environmental risk assessment, human food safety documents and studies, and efficacy studies are accepted	None—pending acceptance
FOI	CVM—FOI—planned in the future with input from UMESC	None—pending acceptance
AOI	PFIZER & NADA Coordinator—AOI—planned in the future after environmental risk assessment, human food safety documents and studies, and efficacy studies are accepted	None—pending acceptance
NADA Package (disease claims)	PFIZER & NADA Coordinator—NADA package—planned in the future after environmental risk assessment, human food safety documents and studies, and efficacy studies are accepted	None—pending acceptance

OXYTETRACYCLINE HYDROCHLORIDE (TERRAMYCIN 343®)

LABEL CLAIM #3

SPECIES: COOLWATER AND WARMWATER FRESHWATER-REARED FINFISH FRY AND FINGERLINGS

INDICATIONS: For the control of mortality in coolwater and warmwater freshwater-reared finfish fry and fingerlings due to systemic columnaris disease associated with *Flavobacterium columnare* (*Flexibacter columnaris*)

DIRECTIONS FOR USE: Apply Terramycin 343® (oxytetracycline hydrochloride) at a concentration of 10 to 40 milligrams per liter [mg/L; equivalent to parts per million (ppm)] in continuous flow water supply of finfish culture units or as a static bath in finfish culture units for 60 minutes daily for three consecutive days.

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Efficacy (systemic columnaris disease/coolwater & warmwater finfish fry & fingerlings)	No entities identified—Efficacy/systemic columnaris disease/coolwater & warmwater finfish fry & fingerlings—plans need to be made	Efficacy—need supportive data; may need funding
Label	PFIZER & NADA Coordinator—Label—planned in the future after environmental risk assessment, human food safety documents and studies, and efficacy studies are accepted	None—pending acceptance
FOI	CVM—FOI—planned in the future with input from UMESC	None—pending acceptance
AOI	PFIZER & NADA Coordinator—AOI—planned in the future after environmental risk assessment, human food safety documents and studies, and efficacy studies are accepted	None—pending acceptance
NADA Package (disease claims)	PFIZER & NADA Coordinator—NADA package—planned in the future after environmental risk assessment, human food safety documents and studies, and efficacy studies are accepted	None—pending acceptance