

AQUACULTURE DRUG APPROVAL DEVELOPMENT STATUS

ERYTHROMYCIN (AQUAMYCIN 100®): RESEARCH AND DEVELOPMENT PLAN AND LABEL CLAIM MATRICES FOR ORIGINAL NEW ANIMAL DRUG APPLICATION (NADA) APPROVALS

1. [Erythromycin \(AQUAMYCIN 100®\) NADA approvals \(none to date\)](#)
2. [Status of technical sections that support all original and supplemental NADA approvals](#)
3. [Label Claim #1: For the control of mortality in freshwater-reared salmonids due to bacterial kidney disease](#)

Rosalie A. 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
Website: <http://aquanic.org/jsa/aquadrugs/index.htm>

**ERYTHROMYCIN (AQUAMYCIN 100®)
(Version 1, November 2007)**

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)]
BIMEDA	Sponsor of Erythromycin—Paul Rice, Bimeda-Osborn, 291 Forest Road, Le Sueur, Minnesota 56058; Phone: 507-665-3316, extension 35; Fax: 507-665-6062; E-mail: paul.rice@bimedadaus.com
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
CVM-OR	Division of Animal Research (HFV-520), Office of Research, Center for Veterinary Medicine, U.S. Food and Drug Administration, Dr. Renate Reimschuessel; Phone: 301-827-8025; E-mail: renate.reimschuessel@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 Program Number Seven—Meg Oeller, CVM Liaison to NRSP-7, 7519 Standish Place, Rockville, MD 20855; Phone: 301-827-3067; Fax: 301-827-4401; E-mail: moeller@cvm.fda.gov
Product Chemistry	Product Chemistry Technical Section includes chemistry, manufacturing, and controls [21 CFR 514.1 (b) (4-6)]
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)
UID	University of Idaho—Dr. Christine Moffitt, Cooperative Fisheries and Wildlife Research Unit, Moscow, Idaho 83844-1136; Phone: 208-885-7047; Fax: 208-885-9080; E-mail: cmoffitt@uidaho.edu

KEY TO COLOR CODING

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

ERYTHROMYCIN (AQUAMYCIN 100®)

Erythromycin (AQUAMYCIN 100®) NADA approvals (none to date)

ERYTHROMYCIN (AQUAMYCIN 100®)

Status of Technical Sections that support all original and supplemental NADA approvals

Technical Section	Entity—Data—Action	Impediments—Action
Product Chemistry	BIMEDA (INAD #11-360)—Product chemistry by agreement with Abbott Laboratories—planned	None—pending acceptance
Product Chemistry (analytical methods)	BIMEDA (INAD #11-360)—Product chemistry/analytical method in feed—in progress	None—pending acceptance
Environmental Safety (ponds, flow-through, & recirculating systems)	UID (INAD #6013) & NRSP-7—Environmental Safety/environmental assessment—submitted final version 5/07; CVM requested changes 10/23/07	None—pending acceptance
Human Food Safety (toxicology)	BIMEDA (INAD #11-360)—Toxicology studies by agreement with Abbott Laboratories—previously accepted	None
Human Food Safety (residue chemistry)	UID (INAD #6013) & CVM-OR—Human Food Safety/bridged official microbial inhibition assay with HPLC method for detection—submitted	None—pending acceptance
Human Food Safety (residue chemistry/all salmonids)	UID (INAD #6013 & PMF #5165)—Human Food Safety/residue chemistry/residue depletion/all salmonids—accepted	None—This Technical Section is complete
Human Food Safety (microbiological effects on bacteria of human health concern/salmonids)	UID (INAD #6013)—Human Food Safety/Guidance Document #152: microbiological effects on bacteria of human health concern/salmonids—accepted 1/07	None—This Technical Section is complete
Human Food Safety (safety of residues in human food/salmonids)	UID (INAD #6013)—Human Food Safety/Guidance Document #159: safety of residues in human food/salmonids—Accepted 11/22/05	None
Target Animal Safety (all salmonids)	UID (INAD #6013)—Target Animal Safety/all salmonids—accepted	None—This Technical Section is complete

ERYTHROMYCIN (AQUAMYCIN 100®)

LABEL CLAIM #1

SPECIES: SALMONIDS

INDICATIONS: [For the control of mortalities in salmonids due to bacterial kidney disease associated with *Renibacterium salmoninarum*](#)

DIRECTIONS FOR USE: Apply AQUAMYCIN 100® in medicated feed at a target dose of 100 mg per kg body weight of fish per day for up to 28 consecutive days.

Technical Section	Entity—Data—Action	Impediments—Action
Efficacy (bacterial kidney disease/all salmonids)	UID (INAD #6013)—Efficacy/bacterial kidney disease/all salmonids—accepted	None—This Technical Section is complete
Label	BIMEDA (INAD # #11-360) & NADA Coordinator—Label—planned with UID & NRSP-7 input	None—pending acceptance
FOI	CVM—FOI—planned with UID & NRSP-7 input	None—pending acceptance
AOI	BIMEDA (INAD # #11-360) & NADA Coordinator —AOI—planned in future with UID & NRSP-7 input	None—pending acceptance
NADA Package	BIMEDA (INAD # #11-360) & NADA Coordinator—NADA Package—planned in future	None—pending acceptance