

GENERAL INFORMATION ON MATRICES FOR TRACKING MAJOR AQUACULTURE DRUG APPROVAL DEVELOPMENT (JANUARY 2006)

Description:

Under the auspices of the Joint Subcommitee on Aquaculture, **Working Group on Quality Assurance in Aquaculture Production** (Working Group), the National Coordinator for Aquaculture New Animal Drug Applications developed "Matrices for Tracking Major Aquaculture Drug Approval Development". These matrices provide detailed information and status on the data and information being developed for the approval of high priority drugs in the United States aquaculture industries. As such, the matrices include the following:

- Contact information on aquaculture drug sponsors
 - Name of sponsored drug
 - Name of company contact
 - Name of company
 - Address of company
 - Phone, Fax, and E-mail addresses
- Code of Federal Regulations references for each Technical Section (i.e., data category)
- Contact information on research institutions
 - Name of research institution contact
 - Name of Research Institution
 - Address of research Institution
 - Phone, Fax, and E-mail addresses
- Matrices
 - Color coded status of each Technical Section needed for approval
 - No current plans and/or funds (RED)
 - In progress or planned (YELLOW)
 - Submitted to CVM (BLUE)
 - Accepted by CVM (GREEN)
 - Status covers several elements
 - Technical Section addressed
 - Entity involved with the numbers for publicly disclosable Investigational New Animal Drug Exemptions (INAD) and/or Public Master Files (PMF)
 - Action taken on each Technical Section
 - Any impediments to approval and action needed (if any)
 - Currently includes 11 high priority aquaculture drugs

Location:

Website for National Coordinator for Aquaculture New Animal Drug Applications:

<http://ag.ansc.purdue.edu/aquanic/jsa/aquadrugs/index.htm> > General Reports >

"Matrices for Tracking Major Aquaculture Drug Approval Development". The matrix or matrices for each drug are web pages that can be downloaded and will be updated periodically. The Working Group's Website: <http://ag.ansc.purdue.edu/aquanic/jsa/wgqaap/index.htm> also contains the matrices and can be accessed by clicking on Presentations and other information and then "Matrices for Tracking Major Aquaculture Drug Approval Development".

Uses:

The "Matrices for Tracking Major Aquaculture Drug Approval Development" can be used by interested parties as follows:

- Determine the status of each drug toward approval
- Provides INAD and/or PMF numbers for other interested entities to access
- Identifies research entities and contact information for drug development by others
- Provides opportunities for funding and planning research by other entities
- Identifies potential bottlenecks impeding approval progress so that solutions can be found