F. NATIONAL COORDINATION FOR AQUACULTURE INVESTIGATIONAL NEW ANIMAL DRUG (INAD) APPLICATIONS

Progress Report
for the period
September 1, 1992 to August 31, 1994

FUNDING LEVEL:

SRAC funding (9/1/93-8/31/94) $2,000
Total funding (9/1/92-8/31/94) $35,180

PARTICIPANTS:

Michigan State University - Robert K. Ringer and Ted R. Batterson

USDA/CSREES, Washington, DC - Henry S. Parker

PROJECT OBJECTIVES:

1. Ensure effective communications among groups involved with INAD applications, including liaison with Canada.

2. Serve as an information conduit between INAD applicants and the U.S. Food and Drug Administration/Center for Veterinary Medicine (FDA/CVM).

3. Champion preparation and submission of INAD applications by affected groups.

4. Seek opportunities for and encourage grouping of applications.

5. Function as an information source for INAD applications.

6. Coordinate educational efforts as appropriate.

7. Identify potential funding sources for INAD activities.

ANTICIPATED BENEFITS:

Investigation and approval of safe therapeutic drugs for use by the aquaculture industry is one of the highest priorities currently facing the industry. At present, only a few approved compounds are available to the industry and further development of the aquaculture industry is severely constrained by a lack of approved drugs essential for treating over 50 known aquaculture diseases. The FDA/CVM has afforded the aquaculture industry throughout the U.S. with a window of opportunity to seek approval of legal drugs to be used in their production practices. The need for additional drugs is great, but securing data necessary to satisfy the requirement of FDA/CVM for drug approval is time consuming, costly, and procedures are rigorous. The obtaining of drugs for legal use through the INAD process is one method the industry can provide FDA/CVM with data on efficacy and also aid the producer in their production practices.

Educating potential INAD applicants will save time and effort for both the industry and FDA/CVM. A National Coordinator for Aquaculture INADs would serve as a conduit between an INAD applicant and the FDA/CVM. The Coordinator would help to alleviate time-demands on FDA staff, thus allowing more time to process a greater number of applications, as well as increasing the breadth of research endeavors within the industry. The grouping of INAD applicants should help to alleviate redundancy, amalgamate efforts, and increase the amount of efficacy data, all of which should result in greater progress toward developing available, approved therapeutic drugs.

PROGRESS AND PRINCIPAL ACCOMPLISHMENTS:

In September 1992, Dr. Robert K. Ringer, Professor Emeritus of Michigan State University, was hired on a part-time basis as National Coordinator for Aquaculture INAD Applications.

Dr. Ringer served in that capacity through August 31, 1994. He also serves as the National Coordinator for USDA's National Research Support Project No. 7 (NRSP-7) for Minor Use Animal Drugs.

As National Coordinator for Aquaculture INADs he participated with FDA/CVM in educational workshops on INAD procedures and requirements. These workshops were conducted throughout the U.S. and attended by several hundred within the aquaculture community. This included workshops held in conjunction with the U.S. Trout Farmers Association, Boston Seafood Show, and Aquaculture Expo V in New Orleans. The workshop at the Boston Seafood Show was videotaped and is now available on cassette from the Northeastern Regional Aquaculture Center. In addition to the workshops, talks were presented on aquaculture drugs at the request of several organizations, including the World Aquaculture Society.

Dr. Ringer also helped in the preparation of a letter that FDA/CVM used in requesting disclosure information from those holding aquaculture INADs. By law, FDA/CVM cannot release any information about an INAD without such permission. As of September 1994, 70 disclosure permissions had been granted. A table containing information about these disclosures was recently made available to the general public. This included the names and addresses of the INAD holders as well as the drug and species of fish intended for use of the drug. It is intended that this table will be periodically updated after additional disclosure permissions have been obtained.

Every effort was made by the National Coordinator to encourage applicant grouping. The Coordinator also provided to INAD applicants specific instructions on proper procedures and requirements for submitting applications to FDA.

It was repeatedly stressed to the aquaculture community that aquaculture INADs are merely a stop-gap measure and efforts must be undertaken to support approval of new animal drugs.

WORK PLANNED:

Dependent upon adequate financial resources, efforts during the next year will focus on New Animal Drug Approvals (NADAs) for aquaculture. A National NADA Coordinator will be hired if the position can be supported at a minimum of a half-time level.

IMPACTS:

Establishment of the National Coordinator for Aquaculture INAD applications has broadened awareness not only of INAD procedures and requirements but also of the need to carry investigations beyond the INAD to gain approval of New Animal Drug Approvals.

As a result of this broadened awareness, the National Research Support Program-7 (NRSP-7) and FDA, sponsored a two-day national workshop Drugs in Aquaculture: Current Status - Future Goals. This workshop was held in Bethesda, Maryland, September 29-30, 1994. Published proceedings of the workshop are forthcoming.

Because of limited funds, this position was only supported on a part-time basis (less than 15%). Therefore, not all intended aspects of coordination were accomplished. The Joint Subcommittee on Aquaculture, Working Group on Quality Assurance in Aquaculture Production, which established the position, has realized the benefits of a National Coordinator for aquaculture drugs. That group is making every effort to establish the position on a full-time basis in the future.

SUPPORT:

Monies to support the National Coordinator for Aquaculture INADs were from a variety of sources. The majority of the funds were provided by USDA's Office of Aquaculture ($25,500). FDA's Office of Seafood Safety provided $3,680. Three of the Regional Aquaculture Centers each provided $2,000: the Northeastern, North Central, and Southern. Additional support for travel for

Dr. Ringer was provided by the Tropical and Subtropical Regional Aquaculture Center and North Carolina State University. Indirect support was also provided from funds for Dr. Ringer's activities as National Coordinator for the NRSP-7.

PAPERS PRESENTED:

Ringer, R.K. 1993. Workshop on INADs, NADAs, and the IR-4 Project. California Aquaculture Association, Oakland, October 11, 1993.

Ringer, R.K. 1993. INAD workshop: Proper drug and chemical use in aquaculture. 9th Annual Florida Aquaculture Association Conference, Fort Pierce, November 6, 1993.

Ringer, R.K. 1994. National INAD Coordinator's role in aquaculture. Aquaculture Expo VII/Annual World Aquaculture Society Meeting, New Orleans, January 13, 1994.

Ringer, R.K. 1994. State of current USDA regulations on drug, therapeutic, and chemical use. North Carolina Aquaculture Development Conference, New Bern, February 5, 1994.

Ringer, R.K. 1994. Investigational New Animal Drugs Workshop. Tropical and Subtropical Regional Aquaculture Center Industry Advisory Council Meeting, Honolulu, Hawaii, March 14, 1994.