



Minor Use Animal Drug Program NRSP-7

A National Agricultural Program
To Approve Animal Drugs for Minor Species

February 12, 2001

Marilyn Broderick,
Freedom of Information Officer, HFV-12,
FDA Center for Veterinary Medicine,
7500 Standish Place,
Rockville, Maryland 20855.

Re: NRSP-7 Policy on Public Availability of Data

Dear Ms. Broderick:

Introduction

The National Research Support Project #7 (NRSP-7) sponsors studies to support the approval of new animal drugs for minor species and minor uses, especially for food- and fiber-producing animals. These studies are conducted using public funds. The data are intended to be placed in the public domain. Recent requests under the Freedom of Information (FOI) Act for data from projects in progress have raised the question of exactly what data are disclosable and when are they disclosable.

Process description

The NRSP-7 program has approximately 25 active projects at any given time. The nature of conducting, writing and submitting the research to FDA's Center for Veterinary Medicine (CVM) for review makes the timing of project completion very hard to estimate. Since different researchers do different parts of each project, it is very common for gaps between efforts to exist. Sometimes projects are inactive for long periods of time and then reinitiated. The timing of publication of the availability of data can cover a wide time frame depending on the success of the research and the priority of the project.

For most projects, NRSP-7 attempts to complete the technical sections for therapeutic effectiveness, target animal safety, human food safety, and environmental safety. These data are generated under the authorization of an Investigational New Animal Drug (INAD) file belonging to NRSP-7. Once all the components are accepted by CVM as sufficient to support approval of a New Animal Drug Application (NADA), a Public Master File (PMF) is created. Typically, the PMF contains the final version of the protocol, the final report, and the CVM letter(s) for each study. It also contains an FOI Summary and some background information about the drug and its proposed use. It does not include the CVM reviews on which the letters are based. A notice of the availability of a complete PMF is published in the Federal Register.

Older PMFs do not always follow the above model. They typically contain much of the information that is now contained in the INAD file. They are often not complete and usually contain CVM reviews, meeting minutes, and other documentation not usually included in more recent PMFs.

The fundamental question of public access to data concerns data that is still in the INAD stage or in PMFs that are not complete. To address this question, NRSP-7 has produced the following guidelines on the definition of public information with regard to data developed in the program.

What is public in the NRSP-7 program?

- The existence of active NRSP-7 projects and their corresponding INAD numbers.
- Public Master Files that have been announced in the Federal Register, exclusive of CVM reviews.
- Data in an INAD that has been reviewed and accepted by CVM once a six-month period from the date of submission to CVM for review has elapsed. This period allows investigators to prepare manuscripts for publication before the data may be placed in the public domain. If CVM review takes longer than six months, the data will not be made public until the review is complete and the data accepted.
- Accepted data in an incomplete PMF, exclusive of CVM reviews according to the same timing guidelines as for the INAD.

Sincerely,

John G. Babish, Ph.D.
National Coordinator
NRSP-7 Program

cc: Dr. Larry R. Miller
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