National Research Support Project-7
(NRSP-7)

A National Agricultural Program for Minor Use Animal Drugs

Action Plan in Response to Five-year Review
1998 - 2003

December 30, 2003

A Review Team consisting of Drs. Sherman. W. Jack, Mississippi State University, Scott A. Brown, Pfizer Animal Health and William W. Saylor, University of Delaware and team leader met at the NRSP-7 Western Regional Laboratories, University of California, Davis, CA on August 19th and 20th, 2003.

The review committee's charge was to examine:

- accomplishments of the program,
- current organizational structure,
- program operations, and
- future programmatic direction.

A report detailing the observations and recommendations of the Review Team was submitted to NRSP-7 on December 23, 2003. Overall, the Review Team found the NRSP-7 program to be a very good program operating in an area of critical and competing needs. The Review Team recommendations offer a mechanism to enhance the interactions between the regional coordinators, stakeholders and FDA/CVM. Additionally, the Review Team recommendations suggest incorporation of additional metrics of productivity to convey the true efficiency and stakeholder responsiveness of the program.

Current NRSP-7 Organizational Structure

The Review Team found the current NRSP-7 organization structure provided for effective management of program operations. The following recommendations relating to stakeholder participation were made to further improve the organizational structure:

Recommendations:

- *The Techncial Committee should seek active participation of stakeholders as ad hoc members of the Technical Committee.*
- *Stakeholders should be invited to be active non-voting participants in at least one of the semi-annual meetings. The nature of the participation could be ad hoc, that is, inviting representatives from different stakeholder groups to meetings on a rotating basis, without representatation from a single or specific group "assigned" to the committee. The Review Team sees this as a critical step to the future of the program. It is suggested that the spring meeting provide the venue for this stakeholder participation, and that the meeting take place within the Washington, DC area to provide the opportunity for the participating stakeholders to visit key legislators on behalf of NRSP-7.*
- *A consortium of MUMS stakeholders should be viewed as a source of capital funding, particularly equipment that might support an array of projects of interest to a broad set of stakeholders. This necessitates the NRSP-7 leaders to coalesce a heretofore disparate set of stakeholders, each with different and individual requests, into a cohesive group interested in working together to provide the infrastructure that would benefit the entire array of stakeholders.*
- *Other avenues to increase outreach/stakeholder participation might include inviting stakeholder representatives to technical committee meetings, providing closer contact during quarterly conference calls between semi-annual technical committee meetings. However, the leading suggestion to increase legislative awareness of the potential of NRSP-7 is to host a "MUMS Night" on capital hill. Discussion of how to organize and proceed to invite key legislators and/or staff for an informative evening would not only inform congressional staff of current activity but also serve to raise awareness of needs and potential*

outcomes of higher and more consistent funding.

Response: Increasing the interaction between NRSP-7 and its stakeholders is an excellent recommendation. In the past, interaction between the program and its stakeholders was primarily through annual symposia dedicated to a single species or stakeholder group such as aquaculture. With increasing cost of travel and decreasing budgets supporting these symposia, this form of stakeholder interaction waned dramatically. The Review Team has suggested a variety of formats to increase stakeholder interaction with the program. First, as recommended by the Review Team, NRSP-7 has reformatted the spring meeting to include participation of several stakeholder groups on an ad hoc basis.

Second, while stakeholders have routinely provided "in kind" support to the program in the form of animals and medicated feed, few have provided capital funding. Increasing the stakeholder base with the inclusion of "ornamental" species and creating a greater degree of interaction with the program as suggested by the Review Team will certainly foster the type of relationships in which stakeholders are willing to provide capital funding. It is strongly felt by the program that, by following the recommendation of the Review Team, significant capital funding could be realized from stakeholders within a period of three to four years.

Program Operation

Recommendation: While the current program operations have been successful in producing remarkable results with limited funding, the Review Team makes the following recommendations that could improve operational efficiency of the program.

- *While the focus of the program should continue to be food- and fiber-producing minor species, the Review Team strongly urges the Technical Committee to expand the mission of the program to include agriculturally-important "ornamental species" (e.g., tropical fish species). The size of the ornamental industries and their contributions to the economy, particularly in some regions, dictate that consideration should be given to including their needs in the scope of the program.*

Response: NRSP-7 has long considered the inclusion of "ornimental species" in the program. Past projects have included honeybees due to their tremendous economic impact in many areas of plant agriculture. The program will initiate further action on this recommendation by modifying the drug request forms to include non-food animals and extend invitations to representatives of the tropical fish and honeybee industries to the 2004 Spring Meeting in Rockville, MD.

Recommendation:

- *The Technical Committee should consider conducting quarterly meetings electronically (e.g., web-conferencing) or by conference call to discuss new ADR's and make decisions on their fate.*

Response: Currently the Technical Committee conducts monthly teleconferences to discuss project management, progress, new ADRs and stakeholder participation.

Recommendation:

- *The Technical Committee should consider organizing the program into regional "Centers of Excellence" for conducting the program's research. While it is important to recognize that each laboratory may have areas of research specialization and the associated facilities and equipment (i.e., for aquaculture research), the program should*

be organized to minimize redundancies, especially in high-end equipment. Areas of specialization could include bioanalytical capabilities, informatics, and in-life activities. Development of centers would optimize the use of the limited resources of the program, help focus program activities, and enable closer monitoring of project progress.

Response: Up to this point, the development of "Centers of Excellence" within the program has been a self-organizing process. However, with this recommendation from the review team, NRSP-7 will begin to actively move toward centralizing critical expertise within the regions. Following upon the recommendation of the Review Team, the program will move forward to organize "Centers of Exellence" in the program. Currently, based upon interest and expertise within the existing regions, the four centers will consist of (1) aquaculture – Northeastern Region, (2) analytical chemistry – Western Region, (3) informatics - Southern Region and (4) disease modeling in minor species – North Central Region.

Funding

The Review Team makes the following **recommendations** about future funding of the program:

- *Because it is unlikely that additional funding can be realized through the regional "off-the-top" funding mechanism, the National Coordinator should limit his activities in this direction. Within the life of the Minor Use Animal Drug Program, no "offf-the-top" funding has been provided to any new program put in place. Hence, it is most unlikely that NRPS-7 will garner support from this funding mechanism.*

Response: The National Coordinator will eliminate travel and expenses associated with eliciting "off-the-top" funding. Other activities with the purpose of providing information regarding the program and overlapping with other objectives will continue. Such activities would include attendance at regional meetings of experiment station directors.

- *The Techncial Committee together with the Administrative Advisors should develop a long-term strategy for providing funding to the program. Past attempts at increases CSREES agency funding have been minimally successful, and probably are not the most effective focus for increased support. Stakeholders must be a significant part of any new initiative. It is suggested that, as part of the stakeholder participation in semi-annual meetings, they are asked to contact and, where feasible, visit appropriate legislators on behalf of the program.*

Response: The development of a long-term strategy for providing funding to the program has been added to the agenda for the 2004 Spring Meeting scheduled for April 26th/27th in Rockville, MD at FDA/CVM headquarters. The new format for this meeting will include stakeholders as previously recommended by the Review Team. These stakeholders will participate in the draft of a 3-year plan for providing outside funding to the program.

Project Management

The NRSP-7 program has historically managed projects by evaluating the ADRs, implementation of the Animal Drug Prioritization Form, and managing activities through various phases of the data-gathering process in a linear fashion (i.e., without progressing the projects along on multiple fronts simultaneously). While this has resulted in a very budget-conscious programmatic approach, the following recommendations are made to enhance efficiency of the process:

- *Modify and simplify the Animal Drug Prioritization Form and the prioritization process. The Team reviewed the form, worked through the prioritization process, and found it to be confusing and cumbersome, particularly the "Product Status Code" assignment and the implications of the code for the future of the drug.*

Response: The National Coordinator agrees that the Animal Drug Prioritization Form and prioritization process is unnecessarily confusing. With the assistance of the Southern Regional Drug Coordinator Dr. Alistair Webb, the National Coordinator will simplify the Form and the process prior to the 2004 Spring Meeting. Along with simplification, the Forms will be modified to encourage submission of requests for non-food animals.

- *Contact the originators of ADR's once a decision on the prioritization has been made, if the originator is outside the NRSP-7 group (e.g. a stakeholder, a pharmaceutical sponsor, etc.). It is important for those providing ADR submissions to the program to learn early of the fate of the request.*

Response: In the past, originators of ADRs were contacted only if they were involved in the progress of the study or on an intermittent basis. The recommendation is excellent and over the next six months, the National Coordinator will contact all originators of ADRs to inform them of the actions taken on their requests.

- *Conduct several areas of research in parallel, in order to speed the time through the process. In particular, focus on ways to reduce the time needed for the most time-consuming segment of the program (often the analytical method development/validation and human food safety studies). In addition, in instances where additional resources may shorten the timeline for completion of the studies, consideration should be given to shifting resources to the rate-limiting activity.*

Response: The program has initiated action on this recommendation through the coordination of florfenicol residue depletion studies in sheep, veal calves and Tilapia. All tissue samples will be analyzed for florfenicol residues at the Western Regional laboratory at the University of California at Davis. This laboratory will also perform the analytical validation and species bridging studies. This parallel format requires the coordinated efforts of three regions, the Western for sheep, North Central for veal calves and Northeastern for Tilapia. Additionally, Efficacy studies, to determine the effective dose in the minor species, must be completed prior to the target animal safety and residue depletion studies. Logistical problems associated with seasonality and timing for efficacy studies must be considered when attempting to conduct several areas of research in parallel. The regional coordinators believe, however, that our current monthly teleconferences provide an effective means for dealing with unanticipated logistical problems and will allow the regions to conduct several areas of research in parallel for other drug-species combinations.

- *The stages of activity could be more carefully monitored not only during the semi-annual Technical Committee meetings, but also in the more frequent teleconferences or web-conferences. Languishing tasks can then be managed more aggressively by the Technical Committee. Furthermore, a process whereby languishing tasks are followed up by the National Coordinator may prompt more diligent attention than what might otherwise occur.*

Response: NRSP-7 has established monthly teleconferences to more closely monitor the activity of projects and CVM reviews.

- *A more rigorous approach to seeking completion of the project through to FDA approval and labeling should allow fewer projects to culminate in the Veterinary Master File. This would include more aggressive efforts with the pharmaceutical industry to complete the administrative tasks of label changes and NADA submission.*

Response: Currently those Public Master Files that have not developed into NADAs are a result of late decisions from the pharmaceutical manufacturer after years of supporting the activities of NRSP-7. Changes in management or loss of market share for the original approval are the most commonly cited reasons from the pharmaceutical manufacturer for the withdrawal of support. In this regard, there is little NRSP-7 can do to exert any pressure to add the label claim for the minor use or minor species. NRSP-7, however, does revisit these manufactures on a yearly basis to ascertain any interest in the data.

Informatics

The Review Team offered that Informatics would be better utilized to increase/improve communication with NRSP-7 participants and stakeholders. Additionally, they suggested that our current The "RUSTI" project tracking system would significantly improve internal progress tracking of projects. Other suggested improvements to web usage include posting pdf versions of publications and or dissertations that have been supported through NRSP7 funds as well as links to other appropriate pages (partners, producer and/or pharmaceutical company websites). Existing brochures and any newly developed media information packages should likewise be posted. Stakeholders can be "surveyed" using the web site.

Response: NRSP-7 has initiated the process of adding links to the Medline references of publications as well as the current links to stakeholder groups. The existing brochure has been added to the NRSP-7 website as a downloadable pdf file.

Outreach

Several recommendations have already been made regarding the need for the Technical Committee to more actively seek stakeholder participation in its activities. This form of outreach is viewed as critical by the Review Team for the future success of the program, particularly in terms of future funding opportunities. The Review Committee makes the following specific **recommendation** for outreach not only to stakeholder groups but also to congressional members and staff:

- *The Technical Committee is encouraged to organize and host a "MUMS Night on Capitol Hill." This event is viewed as an annual opportunity to invite legislators and staff to an informal evening organized to inform them of current activity and to raise their awareness of the needs for increased, more consistent funding. Ideally, such an event could be scheduled during the spring NRSP-7 meeting when congressional budget discussions are underway, and at a time that the stakeholder groups would be attending the NRSP-7 semi-annual meeting in the Washington area.*

Response: The Technical Committee will first examine the feasibility of working with the MUMS (Minor Use Minor Species) coalition for a MUMS Night on Capitol Hill during the 2004 Spring Meeting, which will be attended by several members of the

MUMS coalition. A primary consideration for the development of this type of activity is the fact that a majority of members of the NRSP-7 organization is prohibited from political lobbing activities. The National Coordinator, however, is not and will be appointed at the 2004 Spring Meeting to develop a committee of MUMS coalition members that are representative of NRSP-7 stakeholders to organize a lobbing effort.

Conclusion: NRSP-7 feels that the site visit and Review Team report have made a significant contribution to increasing the efficiency of the program and greatly appreciates the time and effort these individuals provided. The Technical Committee and all persons affiliated with The Minor Use Drug Program believe in its value to stakeholders and the public. We agree with the Review Team that the program is very good and operates in an area of critical and competing needs. We further agree with the considered recommendations of the Review Team and we will work vigorously toward their implementation.

Submitted:

John G. Babish, Ph.D. Date
National Coordinator
Chair, Technical Committee

Donald C. Robertson, Ph.D. Date
Chair, Administrative Advisors