Progress Report on FDAMA and Stakeholder Involvement
Framework for Commissioner's Message to Stakeholders on April 28, 1999

	Describe progress since passage of FDAMA (11/97)	Describe how you involved stakeholders	Describe plans for involving stakeholders in the coming year
FDAMA Objective			

A. Maximize the availability and clarity of information about the process for review of applications and submissions made under this Act.	*Met with sponsors to clarify requirements for mass spectrometry methodology*		*Future meetings will be held with stakeholders as new research issues or questions arise.*
	Since passage of the ADAA CVM has conducted 363 presubmission conferences with sponsors to discuss effectiveness requirements for new animal drugs. [Note: additional presubmission conferences (not included in the 363 above) have been held with sponsors to discuss target animal safety and human food safety issues. Data have not been collected on these meetings because the main thrust of the ADAA was on effectiveness requirements.]	*Direct meeting with stakeholders one-on-one.*	*We will report progress and seek additional input from our stakeholders at our semi-annual meetings.*
	CVM is continuing to update guidance documents concerning the requirements for the new animal drug review process.	*In updating our guidance documents CVM continues to seek and use stakeholder input in the process. In some instances the Center has allowed the stakeholders to develop the first draft of the guidance documents.*	*CVM will continue these cooperative efforts to update guidance documents.*

B. Maximize the availability and clarity of information for consumers and patients concerning new products.	*The Center has held satellite teleconferences to inform our stakeholders about new regulations such as AMDUCA and BSE, and introduced our draft antimicrobial resistance enforcement "framework" through a public meeting of our advisory committee (VMAC).*		
		CVM is continuing to provide education to our stakeholders through our exhibit program, which has been used around the country at significant veterinary professional meetings.	*CVM will continue its current program and increase its efforts to provide information to our stakeholders concerning the antimicrobial resistance issue, as more information is developed through our surveillance program NARMS and our related research program.*
	CVM provides an extensive amount of information at its internet web site.	*Information is continuously provided to stakeholders on how to access our internet web site and what information is located there.*	*CVM will continue to expand the information available and continue our education efforts to inform our stakeholders on the access to and content of our internet web site.*
	CVM has increase its efforts to inform our stakeholders through our two publications, the FDA Veterinarian, and CVM Updates.	*The FDA Veterinarian is provided by subscription and the CVM Updates are provided to an extensive mailing list as well as being posted on our internet web site.*	*CVM will continue to provide these two publications, and continue to expand the use of the CVM Updates in particular.*

C. Implement inspection and post market monitoring of the Act.	*CVM is enhancing our compliance and enforcement efforts by setting new priorities base on risk , focusing efforts based on these priorities to make more efficient and effective use of compliance resources, and increasing surveillance in order to detect emerging problems earlier.*	*CVM received several requests to increase enforcement against illegally marketed, manufactured and compounded animal drugs at our 8/19/98 stakeholder meeting. CVM will seek stakeholder input concerning how to set the risk-based priorities.*	*CVM will continue discussions with stakeholders at our semi-annual stakeholder meeting to monitor progress and to obtain input on our enforcement strategies and risk-based priorities.*
D. Ensure access to the scientific and technical experts needed by the Secretary ...	*Enhanced cooperation between CVM and UDSA scientists particularly for FSI.*	*Recommended by stakeholders at our meeting on 8/19/98.*	*We will report progress and seek additional input from our stakeholders at our semi-annual meetings.*
	Enhanced CVM scientific capabilities by hiring 3 new research scientists with backgrounds in microbial resistance and aquaculture	*Recommended by stakeholders at our meeting on 8/19/98.*	*We will report progress and seek additional input from our stakeholders at our semi-annual meetings.*
	Enhanced CVM scientific capabilities by purchasing state-of-the-art equipment and training in the latest microbial resistance techniques.	*Recommended by stakeholders at our meeting on 8/19/98.*	*We will report progress and seek additional input from our stakeholders at our semi-annual meetings.*
	Funded seven cooperative agreements with scientists outside FDA to study the animal production environment and its relationship to food borne pathogens and development of antibiotic resistance.		
	Coordinating closely with FSIS and ARS in the development of more effective monitoring methods for drug residues.	*Recommended by stakeholders at our meeting on 8/19/98.*	*We will report progress and seek additional input from our stakeholders at our semi-annual meetings.*

E. Establish mechanisms by 7/1/99 for meeting the time periods specified in this Act for the review of all applications and submissions described in subparagraph A and submitted after the date of enactment of the FDAMA.	*Conducting research to determine if we can require fewer animal studies or reduce the number of animals needed in studies to support certain new animal drug applications.*	*Recommended by stakeholders at our meeting on 8/19/98.*	*We will report progress and seek additional input from our stakeholders at our semi-annual meetings.*
	Working for a timely implementation of the Animal Drug Availability Act (ADAA) (The animal drug version of the FDAMA) by developing and publishing the required regulations. Already has had a favorable effect on 78% of new animal drug applications submitted since the ADAA was passed. [Note: While these measures may reduce the review time for most applications these time savings will be much more than off-set by increased workload and recent cuts to the animal drug review staff.]	*Recommended by stakeholders at our meeting on 8/19/98.*	*We will report progress and seek additional input from our stakeholders at our semi-annual meetings.*
	CVM has initiated a process of preforming pathology reviews in support of food safety determinations by contracting that effort to third parties.	*Recommended by stakeholders at our meeting on 8/19/98.*	*We will report progress and seek additional input from our stakeholders at our semi-annual meetings. CVM is working with our stakeholders in the determination of whether other parts of the animal drug review process can also be cost-effectively performed through contracting with third parties.*

F. Eliminate backlogs in the review of applications described in subparagraph A by 1/1/2000.	*Without additional resources for our new animal drug review staff this will be impossible. This takes into account the FY 2000 pre-approval increase which is currently planned for CVM. This increase, while substantial, will return the staff to a level slightly above its FY 98 level.*		
Other: Major initiatives not mentioned above			