Bio
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

March 5, 2010

James C. Greenwood
President & CEO

The Honorable Rosa L. DeLauro
House Appropriations Subcommittee
on Agriculture, Rural Development,
and Food and Drug Administration
2362 Rayburn House Office Building
Washington, DC 20515

The Honorable Jack Kingston
House Appropriations Subcommittee
on Agriculture, Rural Development,
and Food and Drug Administration
1016 Longworth House Office Bldg
Washington, DC 20515

Dear Chairwoman DeLauro and Ranking Member Kingston:

On behalf of the Biotechnology Industry Organization (BIO), I am writing to encourage your support of programs and initiatives of critical importance to our industry. Please support the following requests as you develop the Fiscal Year 2011 Agriculture, Rural Development, Food and Drug Administration and Related Agencies Appropriations Act:

FOOD AND DRUG ADMINISTRATION (FDA)

For FY11, BIO respectfully requests a total of $2.86 billion in budget authority for the FDA as part of the Agriculture, Rural Development, FDA, and Related Agencies Appropriations Act. BIO recognizes the current constraints on government spending, and acknowledges that the FDA received a budget increase while many federal agencies did not. However, upon reviewing the President's proposal, the $146 million increase in budget authority is only sufficient to address inflationary pressures at the Agency and will not enable FDA to add necessary new programs or personnel, which are critical for modernizing and strengthening the FDA.

Human Drugs and Biologics Programs:
BIO supports a strong, fully-funded FDA with the resources necessary to keep pace with rapidly-evolving biomedical science and to make sound regulatory decisions in a timely and efficient manner. For FY11, BIO respectfully requests an increase of $115 million for the Human Drugs program and $49 million for the Biologics program. BIO member companies recognize that a reliable, science-driven regulatory environment fosters innovation, promotes economic competitiveness, and maintains high patient confidence in the integrity of their medicines. For people with devastating diseases and disabilities, roadblocks to getting new cures developed and approved can be a matter of life or death. For patients who are still waiting for treatment options – such as a first-ever broadly-effective treatment for amyotrophic lateral sclerosis, the first new treatment in four decades for lupus, a next generation treatment for multiple sclerosis, or the next miracle product for cancer – nothing is more important than seeing safe and efficacious products developed and approved as efficiently as possible without unnecessary impediments. Moreover, adequate FDA funding is an economic imperative as well as a public health priority. FDA regulates approximately $1 trillion in consumer products, or 25 cents of every U.S. consumer dollar spent, and it is critical to American economic health and competitiveness that FDA has the tools and resources necessary to effectively and efficiently preserve adequate standards for medical product quality.

Reinforce FDA's Scientific Base: FDA's scientific knowledge and expertise is essential for evaluating the safety and efficacy of medical products. However, recent assessments by the Institute of Medicine, the Government Accountability Office, and FDA's own Science Board

have concluded that chronic lack of federal funding in an era of increasing FDA global responsibility has undermined the agency's scientific base and jeopardized the agency's ability to accomplish its core public health mission. The vision of a 21st Century FDA will not be realized in the absence of substantial and sustained increases to FDA's base appropriations. Additional federal funding is critical to FDA's ability to recruit and retain the best and brightest scientists and medical reviewers, modernize the agency's information technology systems, and restore FDA's scientific capacity.

Advance Regulatory Science and Restore Funding for the Reagan-Udall Foundation: In light of the FDA Science Board's assessment that "while the world of drug discovery and development has undergone revolutionary change, shifting from cellular to molecular and gene-based approaches, FDA's evaluation methods have remained largely unchanged over the last half century," the FDA FY11 budget places a renewed emphasis on Advancing Regulatory Science. Regulatory science is a unique and often neglected discipline aimed at developing and assessing modern tools, methods, and standards for evaluating the safety, efficacy and quality of FDA regulated products and BIO supports additional appropriated funding for these activities in FY11.

Ongoing implementation of the Critical Path Initiative is an important component of FDA's larger effort to modernize regulatory science. Through enhanced support of scientific collaboration and the development of modern regulatory tools and scientific approaches, problematic compounds can be identified and discarded earlier in clinical development while safer, more effective, and more personalized medicines can be developed and reach patients without unnecessary delay. However, limited funding in past years has dramatically slowed Critical Path's progress. For FY11, BIO supports $20 million for the Critical Path program.

Recognizing the urgency many patients face, Congress established the Reagan-Udall Foundation for the FDA in 2007 to advance the Critical Path program through private-public partnerships. Under the Food and Drug Administration Amendments Act of 2007 (FDAAA), Congress authorized FDA to transfer funding to the Foundation and also collect private funding. However, recent Appropriations bills have subsequently restricted FDA's ability to transfer federal funding to the Foundation. BIO believes that this promising partnership is best served by a balanced commitment of both private and public funding sources and urges Congress to lift the restriction.

Bolster Import Safety and Global Responsibilities: BIO also recognizes that the agency is under additional workload and stress due to the increasingly global nature of the modern economy and the persistent threat of counterfeit, adulterated, and diverted medical products. However, FDA funding has not kept pace with these new international responsibilities. Drugs and biologics are a small, yet important, element of the larger discussion around import safety and while America's drug supply is the safest in the world, there is more that FDA can do to further secure the supply chain. BIO is supportive of additional funding for post-market foreign inspections.

Modernize Drug Safety Activities: In recent years, Congress has significantly increased FDA's statutory responsibilities, but agency funding to implement these new laws has until recently remained flat. The most recent legislation, FDAAA, modernizes FDA's ability to properly evaluate the benefits and risks of medical products both before and after approval. This landmark legislation will not be successful if it is not accompanied by adequate appropriated funds to implement several key provisions such as the clinical trials databases and the electronic active post-market surveillance system. FDA's ability to operate a modern, scientifically-based safety surveillance program must be strengthened through a commitment to restoring FDA's base resources.

FDA Transparency and Accountability: Additionally, BIO fully supports increased transparency in how new appropriated monies are spent, and clear communications from FDA about the public health benefits that have been achieved with the new funding.

Food Safety

Center for Food Safety and Nutrition (CFSAN): For the Fiscal Year 2010, BIO respectfully requests $955 million for CFSAN and Field Activities. BIO appreciates FDA's continuing commitment to ensuring the safety of the food supply through CFSAN. CFSAN provides important regulatory oversight of new plant biotech varieties intended for food use; however, with the increase in workload for agricultural biotechnology products, BIO recommends that separate personnel be in place to manage early food safety assessments for agricultural biotechnology products.

Veterinary Medicine

Center for Veterinary Medicine (CVM) (Animal Drugs and Feed): BIO strongly supports appropriate funding for CVM, which oversees biotechnology-derived plant products used as, or in, animal feed as well as genetically-engineered animals and their products. The FY 2010 budget for the Center is $135 million. However, additional resources are required for the animal biotechnology program to keep the momentum of the regulatory process for genetically-engineered animals focused toward product approvals, including premarket, postmarket, research, infrastructure, training, communications and field resources. Therefore, BIO recommends the Committee provide $165 million in FY 2011 (an increase of $30 million), of which $10 million should be directed to the animal biotechnology program.

BIO respectfully requests the inclusion of the following specific language:

"The Committee directs $10 million to the FDA, CVM Animal Drugs and Feed budget authority to be expended in the conduct of the animal biotechnology program including premarket, postmarket, research, infrastructure, training, communications and field resources aspects of the program for genetically engineered animals and their products leading toward additional approvals and to allow continued monitoring of the international scientific progress on livestock cloning."

UNITED STATES DEPARTMENT OF AGRICULTURE

Office of General Counsel: BIO supports robust funding for the Office of General Counsel (OGC) and requests that the Committee provide at least $45,654,000. BIO believes additional resources are needed at OGC to handle legal matters resulting from National Environmental Policy Act (NEPA) and Endangered Species Act (ESA) analyses by USDA's Animal and Plant Health Inspection Service (APHIS). BIO has consistently supported a rigorous regulatory system that demonstrates the safety of biotech-derived crops, and continues to do so. However, timely, science-based authorizations are needed to allow farmers access to technologies that they badly need to meet the challenges of modern agriculture. The lack of a sufficient number of staff for legal reviews is significantly hampering the ability of USDA to issue decisions on an increasing number of new products that would be of use to agricultural producers.

Biotechnology Regulatory Services (BRS): Since its inception in June 2002, BRS operates a program that regulates the field testing, movement, and importation of crops and foods improved through biotechnology. This includes coordinating domestic regulation and policy regarding genetically-engineered organisms among U.S. agencies, particularly with USDA, FDA

and EPA. As agricultural biotechnology continues to grow with an increasing number of new products, the workload at BRS is increasing substantially in this area. Further, in light of recent federal court rulings, additional staff to prepare National Environmental Policy Act (NEPA) and Endangered Species Act (ESA) analyses is needed to ensure regulatory decisions keep pace with the evolving technology. Agency resources are currently taxed to the point where it cannot meet its own regulatory timelines. BIO supports increasing BRS' budget to $22.8 million in FY 2011 from $13 million in FY 2010.

APHIS User Fees: With respect to the proposed user fees for APHIS, APHIS regulates the certain aspects of the research and development of agricultural biotechnology products. These are required functions of the government to assess the safety of these products and as such it is inappropriate to require user fees. This proposed user fee represents a tax on an innovative, science-based industry and will negatively impact our industry, therefore BIO urges that the proposed user fees for APHIS not be adopted.

Biotechnology and Trade Activities: BIO believes that maintaining and expanding markets for agricultural biotechnology products is critical to the long-term health and prosperity of the U.S. agricultural sector. Rather than requesting funding for different offices within USDA for biotechnology-related activities, this account was created to provide critical funding for the various agencies involved to provide U.S. leadership globally on matters related to agricultural biotechnology. Additionally, when the FDA and EPA are involved, this account provides for the travel expenses for the representatives of these separate agencies helping to provide needed scientific expertise to countries around the globe. Increased resources should be used proactively to help key developing countries better understand and support a science-based regulatory approach for agricultural biotechnology, thereby promoting regulations that support innovation and agricultural producers to benefit from the technology. Therefore, BIO requests the Committee provide $2.5 million for this account in the FY 2011 budget.

Biorefinery Assistance Program: Authorized in Section 9003 of the Food, Conservation, and Energy Act of 2008, the Biorefinery Assistance Program provides loan guarantees for the development, construction, and retrofitting of commercial-scale biorefineries and provides grants to help pay for the development and construction costs of demonstration-scale biorefineries. BIO supports this program, and encourages the Committee to maintain the FY2010 mandatory funding level of $245 million, as well as provide an additional $150 million in discretionary funding.

The Bioenergy Program: Authorized in Section 9005 of the Food, Conservation, and Energy Act of 2008, this program provides support for the development of conversion technologies for cellulosic biofuels. Eligible producers entering into a contract with USDA are paid based on quantity and duration of advanced biofuel production and on net renewable energy content of the advanced biofuel. The 2008 Farm Bill provides a total of $300 million in mandatory funding for FY2009 to FY2012 ($55 million annually in FY2009 and FY2010, $85 million in FY2011, and $105 million in 2012). BIO requests the Committee maintain the mandatory funding in FY 2011, as well as request provide an additional $25 million in discretionary funding.

Biobased Markets Program: The Farm Security and Rural Investment Act (FSRIA) of 2002 included a mandate for USDA to develop and implement a comprehensive program for designating biobased products. This program, known as the Biobased Markets Program, directs federal agencies to increase their purchase and use of biobased products. This program also establishes a labeling program for biobased products to accelerate commercialization. As the single largest consumer in the United States, purchasing roughly $400 billion annually in goods

and services, the federal government's preferred use of biobased resources will lessen our dependence on foreign-based petroleum sources. We ask that the Committee provide $2 million for this program in FY 2011.

Animal Plant Health Inspection Service (APHIS)

Animal Care (AC): The Animal Care Program determines and promotes standards of humane care and treatment of animals through inspections and educational efforts. Many BIO members are regulated by the USDA under the authority defined in the Animal Welfare Act. In FY 2009, Congress appropriated $22 million to enforce the Animal Welfare Act. BIO supported this increase then, and encourages the Congress to provide $23.8 million in FY 2011.

Veterinary Services, Center for Veterinary Biologics (CVB): CVB plays a vital role in regulating products that diagnose, prevent or treat animal diseases. Every year the U. S. animal health companies produce 83 billion doses of animal vaccines, many which are biotech-derived. These vaccines are critical to protecting the health of America's livestock and pets from domestic and foreign animal diseases. Despite the significant role that CVB plays in global human and animal health, for the past three Fiscal Years, CVB's funding has not met cost of living increases, so no progress has been made in filling vacant positions. The lack of funding at CVB is dire, and threatens the innovation and availability of animal health products. BIO supports the mission for CVB and requests $24.5 million for FY 2011

Foreign Agricultural Service:

One of USDA's strategic goals is to expand global markets and enhance international competitiveness. In recent years, unjustified sanitary and phytosanitary (SPS) trade barriers have been adopted by foreign governments at an alarming rate, including for agricultural biotechnology. While countries may maintain measures to ensure that food is safe for consumers and to prevent the spread of pests or diseases among animals and plants, the measures must be science-based. BIO requests at least $258,780,000 in FY 2011 for the Foreign Agricultural Service.

Food Safety Inspection Service:

Codex Office: To protect the health of consumers, to enhance U.S. trade interests, and to ensure that international standards are based on science, the U.S. Codex Office requires a reliable and adequate budget commitment that is proportional to other developed nations. We respectfully ask for the inclusion of the following language:

"The Committee provides $4.5 million for the activities of the U.S. Codex office, including international outreach and education. The Codex Alimentarius Commission is critical for the protection of consumer health globally and for facilitating trade."

Agricultural Research Service (ARS):

BIO believes that public funding for agricultural biotechnology research conducted through intramural programs of the ARS is critical to the discovery of new biotech solutions toward production of improved, healthful and safe foods that will feed the global population of the future. BIO is concerned that ARS funding has not kept pace with inflation and urges Congress to sustain and enhance ARS funding. In particular, BIO supports research to advance agricultural genomics research in several areas, including livestock and crop production and biofuels

development to provide new technologies that can increase competitiveness and improve agricultural performance and efficiency. For FY 2011, BIO requests Congress provide $1.199 billion to meet these goals.

Regional Biofuels Feedstock Research and Demonstration Centers: BIO supports the President's request for $10 million for the creation of five Regional Biofuels Feedstock Research and Demonstration Centers. These Centers will coordinate efforts for research conducted by other agencies and departments to accelerate the development and deployment of energy feedstocks and sustainable feedstock production systems for advanced biofuels. They will seek out those suited for best participation within different regions across the U.S. by adopted feedstocks.

Cooperative State Research, Education and Extension Service:

BIO supports an appropriation of $500 million for the National Institute for Food and Agriculture (NIFA). Congress should appropriate a substantial boost in NIFA funding to begin the investment toward its authorized level of $700 million. NIFA is the premiere USDA competitive grants program that takes research and innovation beyond the development phase, into implementation through contemporary education and extension programs in areas that include plant health and production, and animal health and production, as well as renewable energy.

Natural Resources Conservation Service:

Biomass Research and Development: Section 9008 of the Food, Conservation, and Energy Act of 2008 is a program that was originally authorized in the 2002 Farm Bill (P.L. 107-171) and is administered jointly by USDA and DOE. It supports research on and development and demonstration of biofuels and biobased products, and the methods, practices, and technologies for their production. The 2008 Farm Bill provides mandatory funding of $118 million for FY2009 to FY2012. The Farm Bill also authorizes the appropriation of $35 million for each of fiscal years FY2009 through FY2012. BIO requests the Committee to maintain the mandatory funding in FY 2011, as well as provide an additional $35 million in discretionary funding.

Rural Development:

Repowering Assistance Program: Section 9004 of the Food, Conservation, and Energy Act of 2008 authorizes payments to encourage existing biorefineries to replace fossil fuels used to produce heat or power for operation of the biorefinery. Payments would be made for installation of new systems that use renewable biomass or for new production of energy from renewable biomass. BIO requests the Committee maintain the mandatory funding in FY 2011, as well as provide an additional $15 million in discretionary funding.

Thank you for your consideration of these requests. Should you have any questions or comments, please feel free to contact Patrick Carroll, Director of Federal Government Relations at (202) 962-6696. We look forward to working with you throughout the appropriations process.

Regards,

James C. Greenwood
President and CEO