Agreement Paves Way For Better, Smarter Regulation Of Biopharmaceuticals

COLLEGE STATION, Texas - ProdiGene, Inc., a leader in the development of biopharmaceutical production and applications, announced that it had reached agreement with the USDA's Animal Plant Health Inspection Service, or APHIS.

The settlement deals comprehensively and finally with allegations arising from activities in Iowa and Nebraska. The agreement also addresses concerns raised by the U.S. Food and Drug Administration.

Anthony Laos, president and chief executive officer of Prodi-Gene, stated that, "We are pleased to put recent allegations behind us, and are optimistic about the future of biopharmaceuticals and their regulation. ProdiGene leads the nation in research and permit applications in this new field. As a result, we expect the enhanced compliance program we are developing in close cooperation with USDA to set the benchmark for regulating the entire industry.

"The future of biopharmaceuticals has simply never been brighter," Laos noted. "Prodi-Gene's proven technology provides safe, non-animal sourced proteins, along with significant economic benefits over traditional production methods. Our technology holds the promise of reducing the cost of production and increasing the availability of pharmaceuticals to better combat diseases like AIDS and to reduce human misery at home and abroad.

'The settlement with the government was not without cost to ProdiGene," Laos further stated. "The settlement will call for us to pay a fine of \$250,000, and to reimburse the government for the cost of destroying 500,000 bushels of soybeans that allegedly came into contact with a tiny amount of corn stalks and leaves. Although USDA has pledged to dispose of the soybeans 'efficiently and economically,' total costs may be in the

millions. Nevertheless, we are confident that ProdiGene will be able to continue the responsible development of biopharmaceutical applications.

"The process of negotiating with USDA has sometimes been trying, but always amicable and professional. USDA even thanked us for our 'cooperation during the process of developing the consent decision and order. USDA has also indicated that it considers the settlement agreement to address finally and



comprehensively all the issues raised in Iowa and Nebraska. Importantly, the allegations alone will not be used as a basis for denying future permit applications," Laos observed, referencing a letter from USDA that was provided to reporters.

"We have learned some valuable lessons," Laos noted, "and we hope the entire industry will benefit from our endeavors as we work with USDA on an enhanced compliance program."

ProdiGene can be reached at (979) 690-8537.





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