

BRS Stakeholder Updates
To:
cc:
Sent by: Judy A Garrison Subject: BRS Stakeholder Update, May 2006

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Dear BRS Stakeholder:
May 10, 2006

Greetings! I'd like to share some important information with you from Biotechnology Regulatory Services (BRS), a program within the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS). BRS recently completed a document to provide guidance on the field testing and movement of genetically engineered organisms for use in making pharmaceutical or industrial compounds. BRS regulates the importation, interstate movement, and release into the environment of regulated genetically engineered organisms, and strengthened its requirements for pharmaceutical and industrial crops in 2003.

Through our *Draft Guidance for APHIS Permits for Field Testing or Movement of Organisms with Pharmaceutical or Industrial Intent*, BRS is consolidating and updating all previously published guidance letters into one concise resource. In the past, we published guidance letters to assist individuals in completing the APHIS Form 2000 permit application, which is required to introduce a pharmaceutical or industrial crop. We hope that the new, consolidated guidance will not only help applicants better understand the application requirements, but also serve to provide transparency to the BRS regulatory process.

The draft guidance will be updated as BRS regulatory policies change. These changes will be highlighted on the BRS Web site. The guidance document, as well as any future changes to it, can be found at <http://www.aphis.usda.gov/brs/pharmaceutical.html>. For more information on how BRS regulates pharmaceutical and industrial crops, please visit http://www.aphis.usda.gov/publications/biotechnology/content/printable_version/BRS_FS_pharmaceutical_02-06.pdf.

We look forward to working with our stakeholders and sharing other important information with you as we further enhance our regulatory program. If you have not previously registered as a stakeholder with BRS, please go to <https://web01.aphis.usda.gov/BRS/BRSWeb.nsf> and sign up to ensure that you receive all future stakeholder letters.

Sincerely,

Cindy J. Smith
Deputy Administrator, Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
United States Department of Agriculture

