The collection of this information is authorized by the Plant Protection Act of 2000. The information will be used to determine eligibility to receive all types of permits. No permit will be issued until this application has been approved.

U.S. DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
BIOTECHNOLOGY REGULATORY SERVICE

APPLICATIONS FOR PERMIT OR COURTESY PERMIT UNDER 7 CFR 340

(Genetically Engineered Organisms or Products)

1. NAME, ADDRESS, TELEPHONE, AND EMAIL OF APPLICANT

Name: Mr. James Smith
Position: CEO
Organization: Premier Enzymes
Organization Unique ID:
Address: 1 State Street
Middletown, IA 00000
County/Province: NOTE: THE APPLICANT AND CONTACT INFORMATION MAY
Township/Island: NOT BE DECLARED AS CBI
Day Telephone: 914-555-1212
FAX:
Alternate:
Email 1: JSmith@email.com
Email 2:

2. INTRODUCTION TYPE

- [x] Importation
- [ ] Interstate Movement
- [ ] Interstate Movement and Release
- [ ] Release

3. PERMIT TYPE

- [x] Standard Permit
- [ ] Courtesy Permit

4. PURPOSE OF PERMIT

- [ ] Industrial Product
- [ ] Pharmaceutical Product
- [ ] Phytoremediation
- [x] Traditional
- [ ] test purpose

5. CONFIDENTIAL BUSINESS INFORMATION VERIFICATION (CBI)

Does this application contain CBI? [x] **Yes** [ ] **No**

CBI Justification:

NOT A VALID PERMIT

APHIS EXAMPLE PERMIT (Importation - Multiple Species - Permit contains Confidential Business Information (CBI))

Legal Background
The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential"("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the release of protected information would likely cause substantial financial competitive harm.

The genetic material (promoters, genes & terminators).
Providing the phenotype description, phenotype, and genetic material inserted and the donors would compromise the time and expense spent in developing the technology to produce the desired trait.

This particular genetic combination is unique because the arrangement is novel and the genetic constructs are themselves novel.

If this information was disclosed, replication by a competitor would cause the loss on many dollars in developing our technology. Furthermore, the competitors would have access to this technology for free at our expense.

6. REQUEST TYPE

[x] **New** [ ] **Amendment** [ ] **Renewal** [ ] **Variance** [ ] **Amendment, Renewal and/or Variance**

Amendment/Renewal Description:
Previous Permit Number(s):

7. MEANS OF MOVEMENT

Common carrier

8. VARIANCE VERIFICATION

Have you previously applied for variance(s) that you wish to apply to this permit? [ ] **Yes** [x] **No**
Variance Number(s):

If so, describe in a brief summary how the variance will be applied:
N/A

WARNING: Any use of ePermits to make materially false, fictitious, or fraudulent statements or representations is subject to civil penalties of up to $250,000 (7 U.S.C. § 7734(b)) or punishable by a fine of not more than $10,000, or imprisonment of not more than 5 years, or both (18 U.S.C. §1001).

9. REGULATED ARTICLE

Scientific Name: Aspergillus niger, Fusarium solani

Common Name:

Cultivar and/or Breeding Line:

Any biological material (e.g., culture medium, or host material) accompanying the regulated Article during movement:
No additional biological material included with regulated material during movement.

Country and locality where the donor organism, recipient organism, and vector or vector agent were collected, developed, and produced:
Paris, France

NOTE: SUPPLIER MAY NOT BE CLAIMED AS CBI IF THE APPLICANT AND SUPPLIER AND/OR DEVELOPER ARE THE SAME.

Processes, Procedures, and Safeguards Description:

10. ARTICLE SUPPLIER AND/OR DEVELOPER

Name	Location	Contact Information
Mr. Richard Smith	00 Rue de Merveilleux Paris 000 France **County:** Ile de France	**Day Telephone:** 00+000+123456 **FAX:** **Email:**

11. PHENOTYPES/GENOTYPE

1) Phenotypic Designation Name:

Identifying Line(s): Aspergillus niger or Fusarium solani NOTE: Construct components may be used in different combinations.

Construct(s): 1-0-1

Mode of Transformation: Protoplast

Phenotype Description:
A description of the anticipated or actual expression of the altered genetic material in the regulated article and how that expression differs from the expression in the non-modified parental organism.

The fungal strains produce [lipases that hydrolze fatty acids and produce green florescent protein. The GFP is a selectable marker for transformation.]

Phenotype(s)

OO - Fatty acid degrading enzyme

Genotype(s)

Gene(s) of Interest
Promoter: [lipase] **from** [Aspergillus oryzae] - native promoter

Promoter: [lipase] **from** [Aspergillus niulans] - native promoter

Gene: [lipase] **from** [Aspergillus oryzae] - Degrades fats.

Terminator: [lipase] **from** [Aspergillus oryzae] - native terminator

Screenable Marker
Promoter: [35s] **from** Cauliflower mosaic caulimovirus - [enhanced 35s function]

Gene: [GFP] **from** Aequorea victoria - [green fluorescent protein used to monitor protein transport in plants]

Terminator: [NOS] **from** [Agrobacterium tumefaciens] - [nopaline synthase from agrobacterium]

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12. INTRODUCTION

Point of Origin

Location Name & Description	Location Address	Contact(s)
1) Institute de Recherche	France	**1)** Mr. Jean Boulanger **Day Telephone:** 33+235+12345

Destination

Location Name & Description	Location Address	Contact(s)
1) American Institute of Science	NOTE: DESTINATION MAY NOT BE CLAIMED AS CBI, IF IT IS THE SAME AS THE APPLICANT'S ADDRESS. NY **County:** Jefferson **Proposed Start Date:** 11/1/2011 **Proposed End Date:** 11/1/2012 **Quantity:** 10 Individual Petri dishes **Inspected by BRS or PPQ?** Yes **Previous Permit No.:** 08-258369rm, 08-1472589m	**1)** John Doe **Day Telephone:** 000-000-000

13. DESIGN PROTOCOLS

Production Design

A detailed description of the purpose for the introduction of the regulated article including detailed description of the proposed experimental and/or production design:

N/A

Destination or Release Description

A detailed description of the intended destination (including final and all intermediate destinations), uses, and/or distribution of the regulated article (e.g., greenhouses, laboratory, or growth chamber location; field trial location, pilot project location; production, propagation, and manufacture location; proposed sale and distribution location):

NOTE: THIS INFORMATION MAY BE CLAIMED AS CBI.

Microbial cultures will moved to the research and manufacturing facility for storage and subsequent growth in culture. There will be no plant inoculation. The cultures will be grown for enzyme extraction and commercial sale.

Confinement Protocols

A detailed description of the proposed procedures, processes, and safeguards which will be used to prevent escape and dissemination of the regulated article at each of the intended destinations:

NOTE: THIS INFORMATION MAY BE CLAIMED AS CBI.

Cultures will be shipped acording to 7 CFR 340.8 (3) Live microorganisms and/or etiologic agents, cells, or subcellular elements. All regulated articles which are live (non-inactivated) microorganisms, or etiologic agents, cells, or subcellular elements shall be packed as specified below:
Volume not exceeding 50 ml (petri plates) will be placed in a securely closed durable plastic box and enclosed in a second, durable watertight container plastic box. The space between the primary and secondary containers contain sufficient nonparticulate absorbent material to absorb the entire contents of the primary container(s). Each set of primary and secondary containers will be enclosed in an outer shipping container constructed of corrugated fiberboard, corrugated cardboard, or other material of equivalent strength.

Final Disposition Method: [x] Destruction/Devitalization [ ] Other [x] Storage in Contained Facility

Final Disposition Description:

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All cultures will be autoclaved or stored in secured storage (limited access, locked storage) for future use.

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14. ATTACHMENTS

15. ADDITIONAL INFORMATION

NOT A VALID PERMIT. APHIS EXAMPLE PERMIT FOR THE IMPORTATION OF MULTIPLE ORGANISMS.

16. COURTESY JUSTIFICATION

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I, *James Smith*, hereby certify that the information in this application and all attachments is complete and accurate to the best of my knowledge and belief.

I acknowledge this is not an application to move or import select agents, the genes expressing select agents, or the toxins made by the select agents, as described in 9 CFR 121.

I will not introduce the regulated articles described in this application until APHIS has deemed the application complete and has granted the permit. By signing this permit, I agree to comply with any and all state, local, and tribal laws and regulations that may apply to the introduction of the articles described in this applications.

If there are any changes to the information disclosed in this application, I will contact APHIS.

17. SIGNATURE OF RESPONSIBLE PERSON	**18. DATE**
James Smith	April 14, 2011

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