

## Greer Receives FDA Approval to Begin Sublingual-Oral Immunotherapy Trial

For More Information Contact:  
Anita Ruka  
Director of Human Resources  
828.754.7849

**FOR IMMEDIATE RELEASE**

**Lenoir, North Carolina, 11.11.2004** – Greer Laboratories, Inc., a leading provider of allergy immunotherapy products and services, has received FDA approval to begin Phase I safety and dosing studies focused on sublingual-oral administration of dust mite allergenic extracts.

Dust mite is one of the most prevalent allergens. Of the roughly 50 million people who suffer from allergies in the United States, approximately 15 percent are sensitive to the dust mite allergens. It is estimated that an additional 10 to 15 million people remain undiagnosed.

Safety and dosing clinical trials are scheduled to begin during the fourth quarter of 2004 and will be conducted by Dr. Robert Bush at The Allergy/Asthma Clinical Research Unit, University of Wisconsin. Subjects will include 24 dust mite-sensitive people between the ages of 18 and 50. The study is expected to last approximately eight to ten weeks.

“The approval to move forward with our safety and dosing trials marks a major milestone for Greer’s R&D sublingual clinical program,” states Bob Esch, PhD Greer Chief Scientist.

### **About Allergy and Immunotherapy**

The WHO (World Health Organization) now classifies allergy as the fourth most important disease in the world and estimates that by 2010, approximately 40 to 50% of the world’s population could be affected.

In the United States, approximately 3 million of the 50 million allergy sufferers are treated with predominantly subcutaneous immunotherapy. Sublingual immunotherapy (SLIT) is delivered via the patient’s oral mucosa.

In Europe, sublingual delivery is widely used. “SLIT is a safe treatment which significantly reduces symptoms and medication requirements in patients with allergic rhinitis.” “Further research is required concentrating on optimizing allergen dosage and patient selection.” according to the The Cochrane Library. Sublingual immunotherapy for allergic rhinitis (Cochrane Review), Issue 4, 2003. In 1998, a panel of experts from the WHO performed an extensive review of the literature and concluded that sublingual immunotherapy (SLIT) was a viable alternative to the injection route and that its use in clinical practice in adults is justified.

“Sublingual immunotherapy is of interest to some allergists because it offers a potential alternative for patients who may not be treated with injection immunotherapy,” states Dr. Spencer Atwater, former President of JCAAI.



Devoted to Allergy Immunotherapy

### About Greer

Greer, established in 1904 located in Lenoir, North Carolina, is a provider of allergy immunotherapy products and services for treating humans and animals. Greer's highly skilled scientists provide technical support for customers by continuing to focus and improve the lives of allergic patients.

Greer's commitment is to expand immunotherapy through sublingual administration in the United States. To learn more about Greer or Greer's other products or services visit us at [www.greerlabs.com](http://www.greerlabs.com) or contact Andrea Marshall Moody, Fleishman-Hillard, Inc. at 919-313-4816 or email [moodya@fleishman.com](mailto:moodya@fleishman.com).