**Written Statement by the Asthma and Allergy Foundation of America**

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**To the Food and Drug Administration Pulmonary-Allergy Drugs Advisory Committee**

**Re: BLA 103976, XOLAIR Omalizumab (Humanized Monoclonal Antibody to Human IgE) For the Treatment of Allergic Asthma**

**May 15, 2003**

On behalf of the over 10 million allergic asthmatic Americans, the Asthma and Allergy Foundation of America (AAFA) appreciates the opportunity to submit written testimony to the Food and Drug Administration's Pulmonary-Allergy Drugs Advisory Committee (FDA PADAC) concerning the benefits of Omalizumab. AAFA is the premier patient organization dedicated to improving the quality of life for people with asthma and allergies. Patients, their families, and their caregivers turn to AAFA for education, research, and patient advocacy. AAFA has not received payment from any entity for this written testimony.

Allergic asthma occurs when an individual is exposed to allergens to which their immune system is sensitive, such as pollen, dust mite proteins, molds, animal dander, and cockroaches. These allergens cause the production of the allergy antibody IgE, one of the first steps in a cascade that causes the airways of sensitive individuals to constrict, increases mucus production, and allows entry of inflammatory cells into the airway. These allergen-induced reactions combine to cause potentially serious asthma attacks in 60% of the 17 million Americans who suffer from asthma.

AAFA supports the development of new and meaningful treatments for those who suffer from all allergies and asthma. In many respects, Omalizumab truly represents a new and meaningful treatment. First, the scientific basis of Omalizumab offers patients hope through an effective mechanism of action that is unlike other existing medications. Second, Omalizumab's efficacy seems to translate directly to an unprecedented high level of quality of life and convenience for patients. Third, Omalizumab offers many allergic asthmatics the ability to gain better control of their conditions and may reduce over time their dependence and use of higher-cost health care services.

Omalizumab is the first bio-engineered drug for severe allergic asthma that stops the allergic biochemical chain reaction before it has a chance to start by binding to and inactivating excess IgE. Successful manipulation of a humanized monoclonal antibody to IgE is a major scientific achievement and clinical advancement.

Omalizumab's clinical effectiveness means that many patients with high anxiety levels might not have to worry as much about the number of control and relief medications they have to take each day or worry as much about making sure these medications are immediately accessible at all times. Omalizumab will have a positive effect by reducing these daily anxieties, thereby increasing quality of life for patients, their families and caregivers.

Moreover, since Omalizumab is injected in the physician's office every 2 to 4 weeks, patients with this difficult to treat asthma will benefit from consistent and appropriate clinical oversight. This will allow patients to take better control of their allergic asthma, perhaps significantly reduce their daily dependence on medications over time, and may help these individuals avoid costly hospital inpatient beds and emergency rooms.

For these reasons, AAFA urges the FDA PADAC to recommend approval of Omalizumab.

Finally, AAFA is concerned about the cost and availability of Omalizumab for patients who might need this medication. The Foundation urges relevant government agencies and the drug manufacturer to establish appropriate care assistance programs to facilitate patient access to Omalizumab. These assistance programs should be made readily and widely available.

Again, AAFA thanks the FDA PADAC for this opportunity to submit written testimony on this important issue.