

## ADDENDUM TO SAFETY BRIEFING DOCUMENT

The following is correction to the FDA Safety Briefing Document (BD) regarding the control group of Omalizumab studies.

On page 11, the BD states,

"Within all the sponsor's clinical studies, anaphylaxis or anaphylactoid reactions were experienced by four subjects exposed to Omalizumab and one subject in a control group."

The correct BD statement should be:

"Within all the sponsor's clinical studies, anaphylaxis or anaphylactoid reactions were experienced by four subjects exposed to Omalizumab and three subjects in control groups."

The following is clarifying information:

Of the four Omalizumab subjects who experienced anaphylaxis/anaphylactoid reactions, temporal association were with the following: one followed levofloxacin exposure and three followed Omalizumab exposure.

Of the three control group subjects who experienced anaphylaxis/anaphylactoid reactions, temporal associations were with the following: one followed peanut exposure, one followed ceftriaxone exposure and one reaction could not be temporally associated with any known allergen/drug exposure.