FDA Statement

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Statement
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Media Inquiries: 301-827-6242
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FDA Statement on Recommendations of the Psychopharmacologic Drugs and Pediatric Advisory Committees

The Food and Drug Administration (FDA) generally supports the recommendations that were recently made to the agency by the Psychopharmacologic Drugs and Pediatric Advisory Committees regarding reports of an increased risk of suicidality (suicidal thoughts and actions) associated with the use of certain antidepressants in pediatric patients. FDA has begun working expeditiously to adopt new labeling to enhance the warnings associated with the use of antidepressants and to bolster the information provided to patients when these drugs are dispensed.

In summary, the members of the advisory committees:

- endorsed FDA's approach to classifying and analyzing the suicidal events and behaviors observed in controlled clinical trials and expressed their view that the new analyses increased their confidence in the results;
- concluded that the finding of an increased risk of suicidality in pediatric patients applied to all the drugs studied (Prozac, Zoloft, Remeron, Paxil, Effexor, Celexa Wellbutrin, Luvox and Serzone) in controlled clinical trials;
- recommended that any warning related to an increased risk of suicidality in pediatric patients should be applied to all antidepressant drugs, including those that have not been studied in controlled clinical trials in pediatric patients, since the available data are not adequate to exclude any single medication from an increased risk;
- reached a split decision (15-yes, 8-no) regarding recommending a "black-box" warning related to an increased risk for suicidality in pediatric patients for all antidepressant drugs;
- endorsed a patient information sheet ("Medication Guide") for this class of drugs to be provided to the patient or their caregiver with every prescription;
- recommended that the products not be contraindicated in this country because the Committees thought access to these therapies was important for those who could benefit; and
- recommended that the results of controlled pediatric trials of depression be included in the labeling for antidepressant drugs.

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