

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

19-839/S-044

20-990/S-010

STATISTICAL REVIEW(S)

09/17/02



**DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH**

STATISTICAL REVIEW AND EVALUATION

NDA: 19,839 /SLR-044
DRUG NAME: Zoloft ® (sertraline hydrochloride)
INDICATION: Major depressive disorder in children and adolescents
SPONSOR: Pfizer
STATISTICAL REVIEWER: Ohidul Siddiqui
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Executive Summary of Statistical Findings

In this new drug application, the sponsor submitted two randomized trials' results to support the efficacy of sertraline in children (6 to 11 years of age) and adolescents (12 to 17 years of age) with major depressive disorder. Based on the primary statistical analysis model (i.e., LOCF analysis on ITT sample), both studies were failed studies with respect to the primary efficacy measure CDRS-R. Therefore, there is no evidence of supporting the efficacy of sertraline for the treatment of children and adolescents with major depressive disorder.

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