

**CLINICAL REVIEW: RELATIONSHIP BETWEEN  
ANTIDEPRESSANT DRUGS AND SUICIDALITY IN ADULTS**

Application Type	NDA
Submission Number	Bupropion (018-644) Citalopram (020-822, 021-046) Duloxetine (021-427) Escitalopram (021-323, 021-365) Fluoxetine (018-936, 021520) Fluvoxamine (75-888,021-519) Mirtazapine (020-415) Nefazodone (020-152) Paroxetine (020-031, 20-710, 20-936, 021-299) Sertraline (019-839, 020-990) Venlafaxine (020-151, 020-699)
Reviewers' Names	Marc B. Stone, M.D. M. Lisa Jones, M.D.
Review Completion Date	November 17, 2006
Established Name	Multiple
(Proposed) Trade Name	Multiple
Therapeutic Class	Multiple Antidepressants
Applicant	Multiple
Formulation	Multiple
Dosing Regimen	Multiple
Indication	Multiple
Intended Population	Users of Antidepressant Products

**Table 16: Suicidal Behavior Risk for Active Drug relative to Placebo – Preparation or Worse –Adults with Psychiatric Disorders – By Drug and Drug Class**

<b>Drug Class</b> Drug	Odds Ratio	95% Confidence Interval	p value
<b>All Drugs</b>	<b>1.10</b>	<b>0.77 - 1.56</b>	<b>0.60</b>
<b>SSRI</b>	<b>1.23</b>	<b>0.82 - 1.85</b>	<b>0.31</b>
Citalopram	1.97	0.56 – 7.00	0.29
Escitalopram	5.67	0.94 – 34.2	0.06
Fluoxetine	1.08	0.52 – 2.23	0.83
Fluvoxamine	1.31	0.51 – 3.38	0.58
Paroxetine	2.76	1.16 – 6.60	0.02
Sertraline	0.25	0.07 – 0.90	0.03
Equality within class	NA	NA	0.03
<b>SNRI</b>	<b>0.83</b>	<b>0.35 – 1.97</b>	<b>0.68</b>
Duloxetine	1.17	0.18 – 7.53	0.87
Venlafaxine	0.69	0.25 – 1.89	0.46
Equality within class			0.62
<b>Other Modern Antidepressants</b>	<b>0.99</b>	<b>0.46 – 2.10</b>	<b>0.97</b>
Bupropion	2.41	0.48 – 12.1	0.29
Mirtazapine	1.25	0.34 – 4.62	0.73
Nefazodone	0.53	0.15 – 1.82	0.31
Equality within class	NA	NA	0.32
Equality across “Newer” drugs	NA	NA	0.12
<b>Tricyclic Antidepressants</b>	<b>0.80</b>	<b>0.38 – 1.68</b>	<b>0.56</b>
Amitriptyline	0	0 - inf	0.98
Clomipramine	0.77	0.14 – 4.15	0.76
Desipramine	0.83	0.07 – 9.89	0.88
Dothiepin	0	0 - inf	0.98
Imipramine	0.85	0.34 – 2.11	0.73
Equality within class	NA	NA	1.00
<b>Other Antidepressants</b>	<b>1.12</b>	<b>0.10 – 12.8</b>	<b>0.93</b>
Mianserin	1.04	0.09 – 12.2	0.98
Trazodone	-	NA	NA
Equality within class	NA	NA	NA
Equality across “Older” drugs	NA	NA	1.00
Equality across All Drugs	NA	NA	0.44
Equality across All Classes	NA	NA	0.81
Equality across All Trials	NA	NA	1.00

Note: all estimates were obtained using conditional logistic regression  
 NA – not applicable