5.2. Tabular Listing of All Clinical Studies

Cymbalta
(Duloxetine Hydrochloride)
Generalized Anxiety Disorder

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Table Abbreviations:

DSM-IV = Diagnostic and Statistical Manual of Mental Disorders, *Fourth Edition*

GAD = Generalized Anxiety Disorder

HAMA = Hamilton Anxiety Rating Scale

MDD = Major Depressive Disorder

No = Number

PO = by mouth

QD = once daily

Table 5.2.1. Tabular Listing of Clinical Studies
Cymbalta (duloxetine hydrochloride)
Generalized Anxiety Disorder

Study Identifier; Location; Status; Report Type	Objectives	Enrollment Start Status End (Total/Goal)	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	No. Patients Completed No. Patients Entered	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint(s)
F1J-MC-HMBR Module 5; Completed; Clinical Study Report	Safety and Efficacy	July 2004 Complete Sept 2005 (639/480)	Multicenter, randomized, double-blind, parallel, fixed-dose, placebo-controlled, Phase 3 study with a single-blind placebo lead-in	Duloxetine 60 mg QD PO Duloxetine 120 mg QD PO Placebo QD PO	389 completed 639 entered	Male and female patients ≥18 years old outpatients meeting DSM-IV diagnostic criteria for generalized anxiety disorder (GAD) and meeting specified disease severity criteria.	9 weeks (acute therapy phase)	Mean change from baseline to endpoint in anxiety symptoms, as measured by the Hamilton Anxiety Rating Scale (HAMA)
F1J-MC-HMDT Module 5; Completed; Clinical Study Report	Safety and Efficacy	Aug 2004 Complete June 2005 (515/320)	Multicenter, randomized, double-blind, flexible-dose placebo-controlled, Phase 3 study with a single-blind placebo lead-in	Duloxetine 60 mg QD PO Duloxetine 120 mg QD PO Placebo QD PO	202 completed 515 entered	Male and female outpatients meeting DSM-IV diagnostic criteria for GAD and meeting specified disease severity criteria	10 weeks (double-blind acute therapy phase)	HAMA (mean change from baseline to endpoint in anxiety symptoms)

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Table 5.2.1. Tabular Listing of Clinical Studies
Cymbalta (duloxetine hydrochloride)
Generalized Anxiety Disorder (Continued)

Study Identifier; Location; Status; Report Type	Objectives	Enrollment Start Status End (Total/Goal)	Design; Control Type	Test and Control Drug(s) Dose, Route, and Regimen	No. Patients Completed No. Patients Entered	Diagnosis or Inclusion Criteria	Treatment Duration	Primary Endpoint(s)
F1J-MC-HMDU Module 5; Completed; Clinical Study Report	Safety and Efficacy	Oct 2004 Complete Nov 2005 (707/480)	Multicenter, randomized, double-blind, flexible-dose, placebo- and active-controlled, Phase 3 study	Duloxetine 20 mg QD PO Duloxetine 120 mg QD PO Venlafaxine extended release 75 to 225 mg QD PO Placebo QD PO	290 completed 707 entered	Male and female outpatients meeting DSM-IV diagnostic criteria for GAD and meeting specified disease severity criteria.	10 weeks	HAMA (mean change from baseline to endpoint in anxiety symptoms)

(continues)

Table 5.2.1. Tabular Listing of Clinical Studies
Cymbalta (duloxetine hydrochloride)
Generalized Anxiety Disorder (Concluded)

Study Identifier; Location; Status; Report Type	**Objectives**	**Enrollment Start Status End (Total/Goal)**	**Design; Control Type**	**Test and Control Drug(s) Dose, Route, and Regimen**	**No. Patients Completed No. Patients Entered**	**Diagnosis or Inclusion Criteria**	**Treatment Duration**	**Primary Endpoint(s)**
F1J-MC-HMDW Module 5; Completed; Clinical Study Report	Safety and Efficacy	April 2005 Complete Jan 2007 (581/560)	Multicenter, double-blind, randomized, placebo- and comparator-controlled, Phase 3 study	Duloxetine 60 to 120 mg QD PO Duloxetine 20 mg QD PO Venlafaxine extended release 75 to 225 mg QD PO Placebo QD PO	299 completed 581 randomized	Male and female outpatients meeting DSM-IV diagnostic criteria for GAD and meeting specified disease severity criteria.	10 weeks	HAMA (mean change from baseline to endpoint in anxiety symptoms)
F1J-MC-HMDV Module 5; Completed; Clinical Study Report	Safety and Efficacy; Relapse prevention study	Jan 2005 Complete Oct 2003 (887/760)	Multicenter, double-blind, randomized, placebo- and comparator-controlled, Phase 3 study	Duloxetine 60 mg QD PO Duloxetine 120 mg QD PO Placebo QD PO	283 completed 887 entered	Male and female outpatients meeting DSM-IV diagnostic criteria for GAD, without major depressive disorder (MDD), and meeting specified disease severity criteria.	Up to 55 weeks	HAMA (time to relapse and mean change from baseline to endpoint)