

US IND 48,395

CELEBREX® (Celecoxib 100 mg, 200 mg, 400 mg)

REGULATORY HISTORY OF SIGNIFICANT EVENTS		
Date	Event	Details
13 July 1995	Original submission of IND 48,395	N/A
09 February 1996	End of Phase I meeting	Clinical development planning
03 May 1996	End of Phase I meeting	Clinical development planning
29 August 1996	End of Phase II meeting	Clinical design for efficacy, long-term safety studies in RA & OA
15 October 1996	End of Phase II meeting	CMC; clinical design for renal studies, platelet studies
04 November 1996	End of Phase II meeting	Clinical design for renal studies and anti-hypertensive drug-interaction studies
12 December 1996	End of Phase II meeting	Labeling, study designs, and statistical considerations
18 February 1997	End of Phase II meeting	Dose-finding. Dose response, indications
22 October 1997	Pre-Phase III meeting	Clinical design of long-term GI studies for COX-2 agents
13 January 1998	Pre-NDA meeting	OA/RA indications
12 February 1999	New protocols submitted	CLASS 1 and CLASS 2 studies initiated (Ph IV commitment)
29 March 1999	Pre-NDA meeting	FAP indication
13 September 2000	Pre-NDA meeting	New pain indications
05 January 2005	Response to FDA Information Request	Alzheimer's Study 001 with addendum (cross reference IND 53,125)

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Submission Date	Submission Type	Details	Approval Date
29 June 1998	Original NDA	Original New Drug Application Indications: osteoarthritis and rheumatoid arthritis in adults	31 December 1998
1 December 1998	N/A	Arthritis Advisory Committee meeting held – data presented for celecoxib and NDA granted priority review	N/A
15 October 1999	Labeling Supplement – CBE	Labeling change: strengthen WARNINGS/Anaphylactoid Reactions	Changes Being Effected
10 June 1999	Labeling Supplement – CBE	Labeling change: strengthen PRECAUTIONS (warfarin co-administration with Celebrex)	Changes Being Effected
24 June 1999	Efficacy Supplement (S-007)	New indication: to reduce the number of adenomatous colorectal polyps in Familial Adenomatous Polyposis (FAP) in patients as an adjunct to usual care. <i>(Note: this indication also filed under NDA 21-156)</i>	23 December 1999
25 April 2000	Labeling Supplement (S-008)	Labeling change: PRECAUTIONS/Pregnancy subsection.	1 December 2000
12 June 2000	Labeling Supplement (S-009)	Labeling change (CLASS): Warnings, Precautions, Adverse Events, and Clinical Studies sections based on a large gastrointestinal outcome study for Celebrex.	7 June 2002
18 December 2000	Efficacy Supplement (S-010)	New indications: management of acute pain in adults and the treatment of primary dysmenorrhea.	18 October 2001
7-8 February 2001	FDA Advisory Committee Meeting	Arthritis Advisory Committee, regarding proposed CLASS labeling supplement S-009	N/A
26 September 2001	General Correspondence - Supplement (S-009)	Formal Dispute Resolution request regarding CLASS labeling	FDA Response to Dispute Resolution (Janet Woodcock) dated 7 December 2001
7 December 2001	N/A	Arthritis Advisory Committee meeting held - for an update on the safety of COX-2 inhibitors which included a presentation of the CLASS data	N/A
12 December 2001	Efficacy Supplement (S-013)	New dosage: 400 mg strength capsules and addition of certain container/closure systems	29 August 2002
9 August 2004	Labeling Supplement (S-017) - CBE	Labeling change: PRECAUTIONS/Drug Interactions, (Warfarin)	Changes Being Effected

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