

**NDA 21-341**  
**BEXTRA (Valdecoxib, 10 and 20 mg Tablet)**

<b>REGULATORY HISTORY OF SIGNIFICANT EVENTS</b>			
<b>Submission Date</b>	<b>Submission Type</b>	<b>Details</b>	<b>Approval Date</b>
16 January 2001	Original NDA	Original New Drug Application	16 November 2001
19 June 2002	Labeling supplement (S-001) – CBE	Modification of text of the Professional Sample carton and sample packaging for the Bextra 10 mg tablet to include the phrase “Once Daily” in association with the product name.	NA letter 24 January 2003
25 October 2002	Labeling supplement (S-002) - CBE	Addition of a new contraindication sentence for patients with a history of allergic reactions to sulfonamides. The addition of a new WARNINGS section: Serious Skin Reactions. The addition of a new sentence to the Warnings-Anaphylactoid Reactions section. The addition of a new paragraph in the ADVERSE REACTIONS section: Postmarketing Experience.	1 November 2002
6 February 2003	Labeling supplement (S-001) – CBE	Withdrawal of unapproved supplemental new drug application for Bextra (valdecoxib sodium) 10 mg tablets.	N/A
24 June 2003	Labeling Supplement (SE-8)	Modification of text of the Product Information to include information from five new drug-drug interaction (DDI) studies conducted with valdecoxib and the following medications: omeprazole, ethinyl estradiol/norethindrone (35 mcg/1 mg combination), phenytoin, diazepam, and glyburide.	23 April 2004
11 August 2003	Labeling Supplement (S-004) - CBE	Draft of the Patient Summary of information for Bextra®.	AE letter 17 March 2004
19 August 2004	Labeling Supplement (S-006) - CBE	Modification of text under WARNINGS Serious Skin Reactions and PRECAUTIONS, Information for patients.	AE letter 14 September 2004
28 October 2004, 12 November 2004, 23 November 2004 (via e-mail)	Labeling Supplement (S-006) - CBE	Addition of Black Box Warning on SSRs, and revised text under the Serious Skin Reaction paragraph of the WARNINGS section. Addition of text discussing safety studies in post-surgical patients (Investigational use) under CLINICAL STUDIES section. The addition of text stating contraindication for the treatment of post-operative pain immediately following coronary artery bypass graft (CABG) surgery under the CONTRAINDICATIONS section. The addition of text under Coronary Artery Bypass Graft paragraph under WARNINGS section.	24 November 2004