Drug Databases (http://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

Postmarket Requirements and Commitments

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You searched for: Both CBER and CDER; Oxaydo; Delayed; Neither

«« « 1 of 1 » »»

Applicant:	ZYLA LIFE SCIENCES US INC
Product:	Oxaydo (Oxycodone Hydrochloride)
NDA/BLA Number:	202080
NDA/BLA Approval Date:	06/17/2011
Annual Report Due Date: (must be submitted within 60 days of this date)	06/17/2026
Annual Report Received:	08/12/2025

Requirement/Commitment Number: 1

Required Under:	FDAAA Section 505(o)(3)
Original Projected Completion Date:	06/30/2016
Description:	PMR 1793-1: An epidemiological study to address whether this formulation of Oxycodone HCl results in a decrease in misuse and abuse, and their consequences: overdose, death and addiction.
Current Status:	Delayed
Explanation of Status:	The final protocol submission, study completion, and final report milestones were missed, because the applicant is working with a consulting firm to address the items noted in the Agency's June 6, 2018, letter. FDA issued a failure to respond letter on 12/23/2022.

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Page Last Updated: 08/09/2013