

2014 (old version)	2016 (new version)	Type of Change	Reason for Change	Burden Change
Blank	Initial Drug Available for LE	Rev	In accordance with section 447.509(a)(4) of the final rule, CMS-2345-F, the Initial Drug Available for LE data definition and valid values are being added.	20 hours per labeler per quarter (this burden change also includes the reporting of the Initial Drug field)
Blank	Initial Drug	Rev	In accordance with section 447.509(a)(4) of the final rule, CMS-2345-F, the Initial Drug data definition and valid values are being added.	20 hours per labeler per quarter (this burden change also includes the reporting of the Initial Drug Available for LE field)
Blank	Line Extension Drug Indicator	Rev	In accordance with section 447.509(a)(4) of the final rule, CMS-2345-F, the Line Extension data definition and valid values are being added.	26 hours per labeler

Type of Change: Rev = Revision, Del = Deletion, Add = Addition, and Red = Redesignation.