

FDA-Approved Marketers of Oxymorphone as of March 2017.				
Labeler Name	Proprietary Name	NDC	Dosage Form	Marketing Category
Actavis Pharma, Inc.	Oxymorphone hydrochloride	0228-3227	TABLET, EXTENDED RELEASE	ANDA
		0228-3228	TABLET, EXTENDED RELEASE	ANDA
		0228-3229	TABLET, EXTENDED RELEASE	ANDA
		0228-3230	TABLET, EXTENDED RELEASE	ANDA
		0228-3261	TABLET, EXTENDED RELEASE	ANDA
		0228-3262	TABLET, EXTENDED RELEASE	ANDA
		0228-3263	TABLET, EXTENDED RELEASE	ANDA
American Health Packaging	Oxymorphone Hydrochloride	60687-148	TABLET	NDA AUTHORIZED GENERIC
Aurolife Pharma, LLC	Oxymorphone Hydrochloride	13107-103	TABLET	ANDA
		13107-104	TABLET	ANDA
Bryant Ranch Prepack	OPANA	63629-4173	TABLET	NDA
		63629-4177	TABLET, EXTENDED RELEASE	NDA
	Opana ER	63629-4174	TABLET	NDA
CorePharma, LLC	Oxymorphone Hydrochloride	64720-258	TABLET	ANDA
		64720-259	TABLET	ANDA
Endo Pharmaceuticals Inc.	Opana	63481-812	TABLET, EXTENDED RELEASE	NDA
		63481-813	TABLET, EXTENDED RELEASE	NDA
		63481-814	TABLET, EXTENDED RELEASE	NDA
		63481-815	TABLET, EXTENDED RELEASE	NDA
		63481-816	TABLET, EXTENDED RELEASE	NDA
		63481-817	TABLET, EXTENDED RELEASE	NDA
		63481-818	TABLET, EXTENDED RELEASE	NDA
	OPANA	63481-624	INJECTION	NDA
Endo Pharmaceuticals, Inc.	OPANA	63481-612	TABLET	NDA
		63481-613	TABLET	NDA
Impax Generics	Oxymorphone hydrochloride	0115-1231	TABLET, FILM COATED, EXTENDED RELEASE	ANDA
		0115-1232	TABLET, FILM COATED, EXTENDED RELEASE	ANDA
		0115-1233	TABLET, FILM COATED, EXTENDED RELEASE	ANDA
		0115-1234	TABLET, FILM COATED, EXTENDED RELEASE	ANDA
		0115-1315	TABLET, FILM COATED, EXTENDED RELEASE	ANDA
		0115-1316	TABLET, FILM COATED, EXTENDED RELEASE	ANDA
		0115-1317	TABLET, FILM COATED, EXTENDED RELEASE	ANDA
KVK-Tech, Inc.	Oxymorphone Hydrochloride	10702-070	TABLET	ANDA
		10702-071	TABLET	ANDA
Lake Erie Medical & Surgical Supply DBA Quality Care Products LLC	OPANA	35356-380	TABLET	NDA
		35356-499	TABLET	NDA
Lake Erie Medical DBA Quality Care Products LLC	Opana	35356-391	TABLET, EXTENDED RELEASE	NDA
		35356-820	TABLET, EXTENDED RELEASE	NDA
		35356-825	TABLET, EXTENDED RELEASE	NDA

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		35356-848	TABLET, EXTENDED RELEASE	NDA
		35356-849	TABLET, EXTENDED RELEASE	NDA
	Oxymorphone hydrochloride	35356-655	TABLET, EXTENDED RELEASE	ANDA
		55700-215	TABLET, FILM COATED, EXTENDED RELEASE	ANDA
		55700-381	TABLET, FILM COATED, EXTENDED RELEASE	ANDA
		55700-387	TABLET, FILM COATED, EXTENDED RELEASE	ANDA
		55700-417	TABLET, FILM COATED, EXTENDED RELEASE	ANDA
		55700-423	TABLET, FILM COATED, EXTENDED RELEASE	ANDA
		55700-441	TABLET, FILM COATED, EXTENDED RELEASE	ANDA
	Oxymorphone Hydrochloride	35356-643	TABLET	ANDA
		35356-967	TABLET	ANDA
		35356-968	TABLET	ANDA
	Mallinckrodt, Inc.	OXYMORPHONE HYDROCHLORIDE	0406-1009	TABLET
0406-1010			TABLET	ANDA
Oxymorphone Hydrochloride		0406-8091	TABLET, EXTENDED RELEASE	ANDA
		0406-8092	TABLET, EXTENDED RELEASE	ANDA
		0406-8093	TABLET, EXTENDED RELEASE	ANDA
		0406-8094	TABLET, EXTENDED RELEASE	ANDA
		0406-8095	TABLET, EXTENDED RELEASE	ANDA
		0406-8096	TABLET, EXTENDED RELEASE	ANDA
		0406-8097	TABLET, EXTENDED RELEASE	ANDA
Par Pharmaceutical	Oxymorphone Hydrochloride	60951-794	TABLET	NDA AUTHORIZED GENERIC
		60951-795	TABLET	NDA AUTHORIZED GENERIC
Physicians Total Care, Inc.	Oxymorphone Hydrochloride	54868-6379	TABLET	ANDA
Ranbaxy Pharmaceuticals Inc.	Oxymorphone hydrochloride	63304-218	TABLET, FILM COATED, EXTENDED RELEASE	ANDA
		63304-219	TABLET, FILM COATED, EXTENDED RELEASE	ANDA
		63304-220	TABLET, FILM COATED, EXTENDED RELEASE	ANDA
		63304-221	TABLET, FILM COATED, EXTENDED RELEASE	ANDA
		63304-222	TABLET, FILM COATED, EXTENDED RELEASE	ANDA
		63304-223	TABLET, FILM COATED, EXTENDED RELEASE	ANDA
		63304-224	TABLET, FILM COATED, EXTENDED RELEASE	ANDA
Rebel Distributors Corp	OPANA ER	21695-948	TABLET, FILM COATED, EXTENDED RELEASE	NDA
		21695-949	TABLET, FILM COATED, EXTENDED RELEASE	NDA
		60760-617	TABLET	NDA
St Marys Medical Park Pharmacy	Opana ER	60760-617	TABLET	NDA
STAT Rx USA LLC	OPANA	16590-765	TABLET	NDA
STAT RX USA LLC	OPANA	16590-609	TABLET, FILM COATED, EXTENDED RELEASE	NDA
		16590-747	TABLET, FILM COATED, EXTENDED RELEASE	NDA
		16590-767	TABLET, FILM COATED, EXTENDED RELEASE	NDA
		0093-5861	TABLET	ANDA
Teva Pharmaceuticals USA, Inc.	Oxymorphone Hydrochloride	0093-5862	TABLET	ANDA
		0054-0283	TABLET	ANDA
West-Ward Pharmaceuticals Corp.	Oxymorphone Hydrochloride	0054-0284	TABLET	ANDA

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NDA= New Drug Application				
ANDA= Abbreviated New Drug Application. (contains data that, when submitted to FDA's Center for Drug Evaluation and Research, Office of Generic Drugs, provides for the review and ultimate approval of a generic drug product.)				
Data from FDA. Extracted but not edited by P. Hasselbacher, MD. KHPI. March 28, 2017				