

**Extended-Release and Long-Acting Opioid Analgesics shared system
RISK EVALUATION AND MITIGATION STRATEGY (REMS)**

Current application holders of the shared system REMS

Product name	Application number	Application holder
morphine sulfate extended-release	ANDA 203849	Actavis Elizabeth LLC
hydromorphone hydrochloride	ANDA 202144	Actavis Elizabeth, LLC
oxymorphone hydrochloride	ANDA 079046	Actavis Elizabeth, LLC
morphine sulfate extended-release	ANDA 079040	Actavis Elizabeth, LLC
Embeda	NDA 022321	Alpharma Pharmaceuticals LLS
fentanyl transdermal system	ANDA 077449	Aveva Drug Delivery Systems, Inc. (An Apotex Company)
Opana ER	NDA 201655	Endo Pharmaceuticals INC
Opana ER	NDA 021610	Endo Pharmaceuticals Inc
oxymorphone hydrochloride	ANDA 079087	Impax Laboratories, Inc.
Nucynta ER	NDA 200533	Janssen Pharmaceuticals INC
Duragesic	NDA 019813	Janssen Pharmaceuticals INC
Avinza	NDA 021260	King Pharmaceuticals LLC
Exalgo	NDA 021217	Mallinckrodt INC The Pharmaceuticals Business of Covidien

oxymorphone hydrochloride	ANDA 202946	Mallinckrodt Pharmaceuticals
fentanyl transdermal system	ANDA 077154	Mallinckrodt Pharmaceuticals
morphine sulfate extended-release	ANDA 076438	Mallinckrodt Pharmaceuticals
morphine sulfate extended-release	ANDA 076412	Mallinckrodt Pharmaceuticals
methadone hydrochloride	ANDA 040517	Mallinckrodt Pharmaceuticals
Methadose	ANDA 040050	Mallinckrodt Pharmaceuticals
morphine sulfate	ANDA 200824	Mylan Pharmaceuticals Inc.
fentanyl transdermal system	ANDA 076258	Mylan Technologies Inc.
morphine sulfate extended-release	ANDA 77855	Nesher Pharms
morphine sulfate extended-release	ANDA 76733	Nesher Pharms
morphine sulfate extended-release	ANDA 76720	Nesher Pharms
fentanyl transdermal system	ANDA 077775	Noven Pharmaceuticals, Inc.
hydromorphone hydrochloride extended-release	ANDA 204278	Paddock Laboratories, LLC
morphine sulfate extended-release	ANDA 200812	Par Pharmaceuticals, Inc.
oxymorphone hydrochloride	ANDA 200792	Par Pharmaceuticals, Inc.
fentanyl transdermal system	ANDA 077062	Par Pharmaceuticals, Inc.
Hysingla ER	NDA 206627	Purdue Pharma LP
Targiniq ER	NDA 205777	Purdue Pharma LP
Oxycontin	NDA 022272	Purdue Pharma LP

Butrans	NDA 021306	Purdue Pharma LP
MS Contin	NDA 019516	Purdue Pharma LP
morphine sulfate extended-release	ANDA 078761	Ranbaxy Laboratories, Inc.
morphine sulfate extended-release	ANDA 074862	Rhodes Pharmaceuticals L.P.
morphine sulfate extended-release	ANDA 074769	Rhodes Pharmaceuticals L.P.
Dolophine	NDA 006134	Roxane Laboratories Inc.
oxymorphone hydrochloride extended release	ANDA 200822	Roxane Laboratories, Inc.
methadone hydrochloride	ANDA 089897	Roxane Laboratories, Inc.
methadone hydrochloride	ANDA 087997	Roxane Laboratories, Inc.
methadone hydrochloride	ANDA 087393	Roxane Laboratories, Inc.
methadone hydrochloride	ANDA 040241	Sandoz Inc.
oxymorphone hydrochloride extended-release	ANDA 203506	Sun Pharmaceutical Industries Limited
morphine sulfate extended-release	ANDA 202718	Teva Pharmaceuticals USA
methadone hydrochloride	ANDA 090635	The Pharma Network, LLC
morphine sulfate extended release	ANDA 202104	Upsher-Smith
morphine sulfate extended-release	ANDA 075295	Vintage Pharmaceuticals LLC, d/b/a Qualitest Pharmaceuticals and a subsidiary of Endo Pharmaceuticals Inc.
Kadian	NDA 020616	Watson Laboratories, Inc.

methadone hydrochloride	ANDA 090707	Watson Laboratories, Inc.
fentanyl transdermal system	ANDA 076709	Watson Laboratories, Inc.
Zohydro ER	NDA 202880	Zogenix INC

Number of total products= 52