

**Buprenorphine Transmucosal Products for Opioid Dependence (BTOD)**  
**waiver-granted shared system**  
**RISK EVALUATION AND MITIGATION STRATEGY (REMS)**

Current application holders of the shared system REMS

<b>Product name</b>	<b>Application number</b>	<b>Application holder</b>
buprenorphine hydrochloride	ANDA 090819	Actavis Elizabeth LLC
buprenorphine and naloxone	ANDA 091422	Actavis Elizabeth LLC
buprenorphine hydrochloride and naloxone hydrochloride dihydrate	ANDA 203136	Amneal Pharmaceuticals
buprenorphine hydrochloride	ANDA 090360	Barr Laboratories INC
Bunavail	NDA 205637	Biodelivery Sciences International Inc.
buprenorphine hydrochloride	ANDA 090622	Ethypharm US COR
buprenorphine hydrochloride	ANDA 201066	Mylan Pharmaceuticals Inc.
Zubsolv	NDA 204242	Orexo US, INC
buprenorphine hydrochloride and naloxone hydrochloride dihydrate	ANDA 078633	Roxane Laboratories INC
buprenorphine hydrochloride and naloxone hydrochloride dihydrate	ANDA 203326	Roxane Laboratories INC
buprenorphine hydrochloride and naloxone hydrochloride dihydrate	ANDA 091149	Teva Pharmaceuticals USA
buprenorphine hydrochloride	ANDA 090279	Sandoz Inc

Number of total products= 12

