

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

210361Orig1s000

MULTI-DISCIPLINE REVIEW

Summary Review

Office Director

Cross Discipline Team Leader Review

Clinical Review

Non-Clinical Review

Statistical Review

Clinical Pharmacology Review

NDA Multi-disciplinary Review and Evaluation

Application Type	NDA – 505(b)(2)
Application Number(s)	210361
Priority or Standard	Standard
Submit Date(s)	August 31, 2017
Received Date(s)	August 31, 2017
PDUFA Goal Date	June 30, 2018
Division/Office	DDDP/ODE III
Review Completion Date	See DARRTS electronic signature page
Established Name	Glycopyrronium
(Proposed) Trade Name	QBREXZA
Pharmacologic Class	Anticholinergic agent
Code name	DRM04
Applicant	Dermira, Inc.
Formulation	Cloth
Dosing Regimen	For topical use only. Apply Qbrexza once daily to both axillae using a single cloth
Applicant Proposed Indication(s)/Population(s)	For the topical treatment of primary axillary hyperhidrosis in adults and children 9 years of age and older
Recommendation on Regulatory Action	Approval
Recommended Indication(s)/Population(s)	Qbrexza is an anticholinergic indicated for topical treatment of primary axillary hyperhidrosis in adults and pediatric patients 9 years of age and older.

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