

Boehringer Ingelheim Ltda. · Santiago · Chile

Boehringer Ingelheim Ltda.
Dirección Técnica

6 de octubre de 2016

REF: Certificación FDA

**Producto: Jardiance Comprimidos Recubiertos 10 mg
Jardiance Comprimidos Recubiertos 20 mg**

Estimados:

Por medio de la presente informamos a Ud, que los productos **Jardiance Comprimidos Recubiertos 10 mg y Jardiance Comprimidos Recubiertos 25 mg** registrados en Chile bajo los N° F-21440/14 y F-21142/14 respectivamente, fue aprobado por la FDA el 01 de agosto 2014, autorización número (NDA) 204629. Se adjunta documento obtenido de la base de datos de la FDA.


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Sin otro en particular, le saluda atte,
BOEHRINGER INGELHEIM LTDA.



Q.F. Claudia Mejías G.
Directora Técnica

 U.S. Department of Health & Human Services




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Drug Details

Drug Name(s)	JARDIANCE
FDA Application No.	(NDA) 204629
Active Ingredient(s)	EMPAGLIFLOZIN
Company	BOEHRINGER INGELHEIM
Original Approval or Tentative Approval Date	August 1, 2014
Chemical Type	1 New molecular entity (NME)
Review Classification	S Standard review drug

There are no Therapeutic Equivalents

Approval History, Letters, Reviews, and Related Documents

Label Information

Products on Application (NDA) #204629

Click on a column header to re-sort the table:


Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
JARDIANCE	EMPAGLIFLOZIN	10MG	TABLET;ORAL	Prescription	No	None
JARDIANCE	EMPAGLIFLOZIN	25MG	TABLET;ORAL	Prescription	Yes	None

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