

Boehringer Ingelheim Ltda. · Santiago · Chile

Boehringer Ingelheim Ltda.
Dirección Técnica

6 de octubre de 2016

REF: Certificación FDA
Producto: Spiolto Respimat Solución Para Inhalación

Estimados:

Por medio de la presente informamos a Ud, que el producto **Spiolto Respimat Solución Para Inhalación** registrado en Chile bajo el N° F-22053/15, fue aprobado por la FDA el 21 de mayo 2015, autorización número (NDA) 206756. 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)	STIOLTO RESPIMAT
FDA Application No.	(NDA) 206756
Active Ingredient(s)	OLODATEROL HYDROCHLORIDE; TIOTROPIUM BROMIDE
Company	BOEHRINGER INGELHEIM
Original Approval or Tentative Approval Date	May 21, 2015
Chemical Type	4 New combination
Review Classification	S Standard review drug

There are no Therapeutic Equivalents

Label Information

Approval History, Letters, Reviews, and Related Documents

Products on Application (NDA) #206756

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


Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
STIOLTO RESPIMAT	OLODATEROL HYDROCHLORIDE; TIOTROPIUM BROMIDE	EQ 0.0025MG BASE/INH; EQ 0.0025MG BASE/INH	SPRAY, METERED;INHALATION	Prescription	Yes	None

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