

Boehringer Ingelheim Ltda. · Santiago · Chile

Boehringer Ingelheim Ltda.
Dirección Técnica

6 de octubre de 2016

REF: Certificación FDA

Producto: Spiriva Respimat Solución Para Inhalación 2,5 mcg/Pulsación

Estimados:

Por medio de la presente informamos a Ud, que el producto **Spiriva Respimat Solución Para Inhalación 2,5 mcg/Pulsación** registrado en Chile bajo el N° F-17708/14, fue aprobado por la FDA el 21 de mayo 2015, autorización número (NDA) 207070. 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)	SPIRIVA RESPIMAT
FDA Application No.	(NDA) 207070
Active Ingredient(s)	TIOTROPIUM BROMIDE
Company	BOEHRINGER INGELHEIM
Original Approval or Tentative Approval Date	September 15, 2015
Chemical Type	9 New indication submitted as distinct NDA, consolidated with original NDA after approval
Review Classification	S Standard review drug

There are no Therapeutic Equivalents

Label Information

Approval History, Letters, Reviews, and Related Documents

Products on Application (NDA) #207070

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


Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
SPIRIVA RESPIMAT	TIOTROPIUM BROMIDE	2.5MCG	SPRAY;INHALATION	Prescription	No	None

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