

Santiago, 2018

De : Q.F. María José Andaur Constanzo
Asistente Asuntos Regulatorios Seven Pharma Chile S.p.A.
A : A quien corresponda.

Estimados,
Mediante el presente, informamos que el producto:

- **LEVOCETIRIZINA DICLORHIDRATO COMPRIMIDOS RECUBIERTOS 5 mg, registro ISP F-22684/16**

Cuyo principio activo es:

- **LEVOCETIRIZINA DICLORHIDRATO**

Cuenta con aprobación de la FDA.

La planta fabricante del producto terminado en Chile y Estados Unidos es HETERO LABS LIMITED UNIT-III, ubicada en Formulation Plot N° 22-110 IDA, Jeedimeetla, Dist. Hyderabad 500 055, Telangana, India.

A continuación se adjunta ficha técnica de registro obtenida desde la página virtual de FDA.

Saludos cordiales.

Q.F. María José Andaur Constanzo
Asistente Asuntos Regulatorios
Seven Pharma Chile S.p.A.

Drugs@FDA: FDA Approved Drug Products

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Abbreviated New Drug Application (ANDA): 091264

Company: HETERO LABS LTD III

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Products on ANDA 091264

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD
LEVOCETIRIZINE DIHYDROCHLORIDE	LEVOCETIRIZINE DIHYDROCHLORIDE	5MG	TABLET;ORAL	Prescription	AB	No

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[Approval Date\(s\) and History, Letters, Labels, Reviews for ANDA 091264](#)



[Therapeutic Equivalents for ANDA 091264](#)



