



Julio 2018

A QUIEN INTERESE:

El titular que suscribe certifica que el producto **COSOPT Solución Oftálmica con principio Activo CLORHIDRATO DE DORZOLAMIDA 20 mg/mL + Maleato de Timolol 5 mg/mL (Registro ISP Nro. F-1875)** el cual se exporta a Chile a su titular ALPES CHEMIE S.A, es un productos **APROBADO POR LA FDA** y es un producto **REFERENTE INTERNACIONAL**.

Se extiende el presente certificado a petición del titular de los registros en Chile.

Cordialmente,

A handwritten signature in blue ink, consisting of a stylized 'A' and 'C' intertwined.

Alba Rocio Castillo Pabón – Q.F. & MSc.
Gerente Regional Asuntos Regulatorios & D.T.
Colombia, Países Andinos y Cono Sur



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Drug Details

Drug Name(s)	COSOPT
FDA Application No.	(NDA) 020869
Active Ingredient(s)	DORZOLAMIDE HYDROCHLORIDE; TIMOLOL MALEATE
Company	OAK PHARMS INC
Original Approval or Tentative Approval Date	April 7, 1998
Chemical Type	4 New combination
Review Classification	S Standard review drug

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Products on Application (NDA) #020869
Click on a column header to re-sort the table:

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLDTE Code
COSOPT	DORZOLAMIDE HYDROCHLORIDE; TIMOLOL MALEATE	EQ 2% BASE; EQ 0.5% BASE	SOLUTION/DROPS; OPHTHALMIC	Prescription	Yes AT

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FAREVA LA VALLEE	3003121602	266951006	API MANUFACTURE; LABEL; MANUFACTURE; PACK;	Zone industrielle de Blavozy, St Germain Laprade, 43700, France (FRA)	12/31/2017

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ZACH SYSTEM SPA	3002808541	517259979	API MANUFACTURE;	VIA DOVARO 2, LONIGO, VICENZA 36045, Italy (ITA)	12/31/2017

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