

**Institute of Public Health  
Ministry of Health**

**Government of Chile**

Reference N°: N738750/16

JMC

**Exempt Resolution RW N° 1762/16**

Santiago, January 26<sup>th</sup> 2016

**SEEN THESE ANTECEDENTS:** The request of Mrs. Paulina Alicia Alegría Madrid, Technical Manager and Mr. Hans Berner Soto, Legal Representative of Opko Chile SA, entered under the reference number N738750, dated January 19<sup>th</sup> 2016, requesting that the renewal of the Marketing Authorization of pharmaceutical CARVEDILOL TABLETS 25 mg; the payment of the corresponding customs duties, by proof payment N° 2016011996333600 issued by Treasury General of the Republic; and

**CONSIDERING:**

**FIRST:** That by submission dated January 19<sup>th</sup> 2016, Mrs. Paulina Alicia Alegría Madrid, Technical and Mr Hans Berner Soto, Legal Representative of Opko Chile S.A., renovation of Marketing Authorization of pharmaceutical product CARVEDILOL TABLETS 25 mg, granted by the Institute of Public Health by Exempt Resolution N° 2789, dated March 4<sup>th</sup> 2011.

**SECOND:** That notes the payment of the corresponding customs duties, by proof payment N°2016011996333600, issued by Treasury General of the Republic, dated on January 19<sup>th</sup> 2016;

**BEARING IN PRESENT:** the provisions of Article 96° of the Health Code, Article 12° of the Regulation of the National System of Control of Pharmaceutical Products, approved by Supreme Decree N° 3 of 2010, the Ministry of Health; in exercise of the powers vested in me by Articles 59° letter b) and 61° letter b) of the Decree with Force N° 1 Act, 2005 and delegated by Exempt Resolution N° 292 of February 12<sup>th</sup> 2014, the Institute of Public health of Chile, states the following:

**RESOLUTION**

1.- **RENEWS** on behalf of Opko Chile S.A., the Marketing Authorization of pharmaceutical product then follow:

Product Name	Prior Marketing Authorization N°	Renewed Marketing Authorization N°	Renewal Date
CARVEDILOL TABLETS 25 mg	F-18528/11	F-18528/16	04-03-2016

2.- This resolution only records modification of Marketing Authorization N°, maintaining current approved mentions in the prior Marketing Authorization, so that any other modification must be expressly authorized.

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3.- The renewal of this Marketing Authorization expires on March 4<sup>th</sup> 2021, of according to the registration date of Authorization, for which the holder of the Marketing Authorization must apply for renewal within 90 days prior to expiration of Marketing Authorization, mentioned in this resolution.

**WRITE AND COMMUNICATE IT**

**DRA. Q.F. HELEN ROSENBLUTH LÓPEZ  
HEAD (S)  
DEPARTMENT  
NATIONAL AGENCY FOR DRUGS  
INSTITUTE OF PUBLIC HEALTH**