

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**21-978**

**ENVIRONMENTAL ASSESSMENT**

#### 1.12.14 Environmental Impact

Connetics Corporation states that the proposed New Drug Application (NDA) for Desonide Foam, 0.05% complies with the categorical exclusion criteria of 21 CFR 25.31(b), and to the best of our knowledge no extraordinary circumstances exist under 21 CFR 25.21.

Desonide is a known drug active which is already on the market in the US.

The projected addition of the active moiety into the aquatic environment based on maximum yearly consumption of this product would result in an insignificant increase based on a maximum projected active usage of 15.4 kg of active ingredient per year.

The total amount of the active moiety introduced into the aquatic environment (EIC) as a result of use of this product is estimated at no more than 0.00035 ppb—well below the allowable EIC of 1 part per billion.

Calculation of total amount of active moiety:

EIC-Aquatic (ppb)<sup>1</sup>  $A \times B \times C \times D$  where

- A kg/year produced for direct use (as active moiety)
- B 1/liters per day entering POTWs<sup>2</sup>
- C year/365 days
- D  $10^9$  µg/kg (conversion factor)

<sup>1</sup> Per Guidance for Industry, Environmental Assessment of Human Drug and Biologics Applications 1998, Section 3.A.2

<sup>2</sup>  $1.214 \times 10^{11}$  liters per day entering publicly owned treatment works (POTWs)