

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**22-007**

**ENVIRONMENTAL ASSESSMENT**

rec'd 6/29/06

### Environmental Analysis

This NDA for Formoterol Fumarate Inhalation Solution 20 mcg/2 mL qualifies for categorical exclusion from performing an environmental assessment report (21 CFR part 25 and Guidance for Industry "Environmental Assessment of Human Drug and Biologics Applications", Revision 1 July 1998). Categorical exclusion is based on the fact that the estimated concentration of the substance at the point of entry into the aquatic environment will be less than one (1) part per billion (ppb). This estimation was determined using the following equation provided in the above mentioned guidance document:

$$A \times B \times C \times D = \text{EIC-Aquatic (ppb)}$$

Where:

A = Kg/year produced for direct use (as active moiety) = 2 Kg/year

B = 1/liters per day entering POTWs\*

C = year/365 days

D =  $10^9$  mcg/Kg (conversion factor)

EIC = expected introduction concentration of the active moiety into the aquatic environment

\*  $1.218 \times 10^{11}$  liters per day entering publicly owned treatment works (POTWs), source: 1996 Clean Water Needs Survey Report to Congress. Information regarding this report is available on the Internet at <http://www.epa.gov/owm>.

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**Calculation:**

$$A = (100,000,000 \text{ vials/ year})(20 \text{ mcg/vial})(1\text{Kg}/10^9 \text{ mcg}) = 2 \text{ Kg/ year}$$

$$B = 1/ \text{L water per day entering POTWs} = 1 \text{ day/ } 1.218 \times 10^{11} \text{ L}$$

$$C = 1 \text{ year/ } 365 \text{ days}$$

$$D = 10^9 \text{ mcg/kg}$$

$(2 \text{ kg/y}) \times (1/1.218 \times 10^{11} \text{ L/day}) \times (y/365 \text{ days}) \times (10^9 \text{ mcg/kg}) = 4.5 \times 10^{-5}$   
mcg/L (< 1 ppb) of Formoterol Fumarate released into the aquatic environment assuming a worse case scenario.

Therefore, Dey requests a categorical exclusion for an environmental assessment as allowed within 21 CFR 25.31(b). Dey is in compliance with all applicable federal/national, state, and local environmental regulations.

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