CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

202450Orig1s000

ENVIRONMENTAL ASSESSMENT

1.12.14 Environmental Assessment

Pursuant to 21 CFR 25.15(d) and 21 CFR 25.31(b), Forest Laboratories, Incorporated (Forest) hereby requests a categorical exclusion from the requirements of an Environmental Assessment for its product, Aclidinium bromide Inhalation Powder, 400 µg. Under 21CFR§25.31(b) a categorical exclusion exists for:

"Action on an NDA, abbreviated application, or a supplement to such applications, or action on an OTC monograph, if the action increases the use of active moiety, but the estimated concentration of the substance at the point of entry into the aquatic environment will be below 1 part per billion."

The Agency's approval of the application increases the use of the active moiety (aclidinium bromide), but the estimated concentration of the substance at the point of entry into the aquatic environment will be below 1 part per billion (ppb).

The estimated concentration of aclidinium bromide at the point of entry into the aquatic environment has been calculated using the formula provided in the FDA "Guidance for Industry: Environmental Assessment of Human Drug and Biologics Applications" dated July 1998. Forest certifies that the maximum Expected Introduction Concentration (EIC) from patient use of Aclidinium bromide Inhalation Powder entering into the aquatic environment is less than 1 ppb and is unlikely to have a significant effect on the environment.

The expected introduction concentration (EIC) of an active moiety into the aquatic environment is provided Table 1.12.14-1.

Table 1.12.14–1. EIC – Aquatic (ppb) = A x B x C x D

where	A = kg/year produced for direct use (as active moiety) B = 1/litres per day entering POTWS* C = year/365 days D = 10^9 µg/kg (conversion factor)
* (b) (4) x 10^{11} liters per day entering publicly owned treatment works (POTWs). (*1996 Needs Survey, Report to Congress)*	
EIC	= (b) (4) x ((b) (4) x 10^{-12} day/L) x ((b) (4) x 10^{-3} year/day) x (1 x 10^9 µg/kg) = (b) (4) ppb or (b) (4) ppm

Product	# of inhalers/year	API (µg/inhaler)	API (kg/year)	EIC (ppb)
Aclidinium bromide Inhalation Powder, 400 µg	(b) (4)			

a Based on forecast volume