

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-157

ENVIRONMENTAL ASSESSMENT

DX-LVT-XXX-BU-2 (EA US)



UCB Farchim SA Z.I. de Planchy 10, Chemin de Croix Blanche P.O. Box 411 CH-1630 Bulle, Switzerland

TO WHOM IT MAY CONCERN

In the framework of the Environmental Assessment for Levocetirizine dihydrochloride:

I, the undersigned, acting on behalf of UCB Farchim SA, Z.I de Planchy, 10 Chemin de la Croix Blanche, 1630 Bulle, Switzerland, where **Levocetirizine dihydrochloride** is manufactured, inform you that the highest quantity of the active moiety expected to be produced for direct use in any of the next five years to be used in the drug product marketed in the USA is expected to be 6750 kg which corresponds to the following forecast:

2007 : 750 kg
2008 : 1500 kg
2009 : 1500 kg
2010 : 1500 kg
2011 : 1500 kg

Bulle, 23rd January 2007

A handwritten signature in black ink, appearing to read 'Luca Ballerini'.

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