

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
200795Orig1s000

ENVIRONMENTAL ASSESSMENT



ENVIRONMENTAL CERTIFICATION LETTER
Mulgrave, Australia

The drug product covered by this application is identical, similar or related in chemical structure, known pharmaceutical properties, and indications for use to drugs which are already being marketed, and there is no reason to conclude that marketing of such additional drug products will change the overall use pattern of the active moiety.

Pursuant to 21 CFR 25.31(a), Hospira hereby claims a categorical exclusion from the requirement of an Environmental Assessment.

A handwritten signature in black ink, appearing to read "Damian Renahan", written over a horizontal line.

Damian Renahan
Manager, Environmental Health and Safety
Hospira Australia Pty Ltd.
1 Lexia Place
Mulgrave
Victoria, 3170
Australia

11 / 02 / 09
Date