

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-260

ENVIRONMENTAL ASSESSMENT



150 ALLEN ROAD, LIBERTY CORNER, NJ 07938 (908) 504-1300

ENVIRONMENTAL IMPACT ANALYSIS STATEMENT

In accordance with 21 CFR 25.31 (a), the sponsor claims categorical exclusion from the requirement for the preparation of an Environmental Assessment on the basis that approval of this ANDA will not increase the use of the active moiety.

A handwritten signature in cursive script, reading "Robert J. D'Angelis", written over a horizontal line.

Robert J. D'Angelis
Director, Regulatory Affairs
GeneraMedix Inc.

August 22, 2007

Date