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APPLICATION NUMBER:

22-350

ENVIRONMENTAL ASSESSMENT



Food and Drug Administration
CDER, Office of New Drug Quality Assessment
Mail Room 2562
10903 New Hampshire Ave.
Silver Spring, Maryland 20993
(301) 796-1679
(301) 796-9747 (FAX)

MEMORANDUM

DATE: 25-JUN-2009
FROM: John C. Hill, Ph.D., CMC Reviewer
THROUGH: Ali Al-Hakim, Ph.D., Chief, DPA-I
TO: File, NDA 22-350
SUBJECT: Environmental Assessment (EA) waiver

The applicant has provided calculations indicating that they are in compliance with the following section of the CFR.

21 CFR§25.31(b) 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 the 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.

This statement is satisfactory, the claim for exemption from the requirement for an EA (21 CFR§25.15) is granted.

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this page is the manifestation of the electronic signature.**

/s/ .

John C. Hill
6/25/2009 11:01:32 AM
CHEMIST

Ali Al-Hakim
6/25/2009 04:31:49 PM
CHEMIST