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HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Polyhexamethylene Biguanide (Baquacil): Review of Data Submitted by
the Registrant in Connection with a Two-Year Carcinogenicity Study in Mice

P.C. Code: 111801
Submission: S459219
MRID No: 431213-01
DP Barcode: D199715

FROM: Timothy F. McMahon, Ph.D., Pharmacologist *Timothy F. McMahon 3/21/94*
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TO: Kathryn Scanlon/ PM 53
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THRU: Yiannakis M. Ioannou, Ph.D., Section Head *Y.M. Ioannou 3/21/94*
Review Section I, Toxicology Branch II
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and

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Toxicology Branch II
Health Effects Division (7509C) *M. Van Gemert 3/22/94*

Registrant: Zeneca, Inc.

Action Requested: Examination of data submitted in connection with a two-year carcinogenicity study with Baquacil conducted in mice.

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Data Summary:

A submission entitled, "Polyhexamethylene Biguanide: Two-Year Oncogenic Study in Mice - Summary for Weeks 27-43 and 44-59" was submitted to Toxicology Branch II in response to a request made by Dr. Timothy F. McMahon, Pharmacologist, Toxicology Branch II. The request for this information was made in response to information supplied by the registrant detailing a mis-dosing which occurred during the conduct of the two-year mouse carcinogenicity study with Baquacil.

Originally, in a phone conversation between Dr. Timothy McMahon and Dr. Mark E. Burt, Chemical Regulatory Specialist, Zeneca, Inc., a mis-dosing event was described by Dr. Burt in which mice were dosed with a dietary mixture belonging to another mouse carcinogenicity study being conducted at the same time. The events surrounding the mis-dosing were detailed in a letter provided to Dr. McMahon, dated November 5, 1991 (copy on file with Dr. McMahon). In response to this letter, Dr. McMahon requested information from the registrant regarding the mouse study conducted with Baquacil. Specifically, information on mortality, clinical signs, body weight, food consumption, hematology, and any other available information was requested which covered the period just prior to and following the mis-dosing event in the study. This information was requested in order to make comparisons between the Toxicology data for the time period surrounding the mis-dosing event and the Toxicology data for the study as a whole, to determine if the mis-dosing event had any significant impact on the outcome of the study.

The present submission contains the requested information, but formal review of these data will not be done until submission of the final report on the two-year study. An informal examination of the submitted data appear to indicate that the mis-dosing did not result in any significant new toxicity. However, as stated, this conclusion can only be tentative in the absence of the final report.