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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

MAR 1 8 1992

MEMORANDUM

OFFICE OF

Review of Supplemental Information on Historical Control SUBJECT:

Skeletal Variations in the Metam Sodium Rat Teratology

Study Addendum to MRID 41577101

TO:

Tom Myers PM 52 SRRD (H7508C)

FROM:

K. E. Whitby, Ph.D. (3/13/92 Section, II

Toxicology Branch II/(HED) (H7509C)

K. Clark Swentzel & Clark Arestet 3/13/92

THRU:

Section Head

Toxicology Branch II/(HED) (H7509C)

and

Marcia van Gemert, Ph.D.

nhan Ernert 3/13/92 Chief, Toxicology Branch II/(HED) (H7509C)

HED Project # 2-1248

Caswell No. 780

<u>Action Requested:</u>

Please review the attached historical control data on skeletal variations for developmental toxicity in the rat as requested by the peer review committee. This information is an addendum to MRID 41577101, Rat Teratology Study.

ICI Americas Inc., has submitted on behalf of the Metam Sodium Task Force, supplemental information on historical control data for skeletal variations in the metam sodium rat teratology study. data which has been submitted does not provide information on the species, strain, source, vehicle treatment, number of studies used to generate the data, the inclusive dates, or the number of fetuses and litters. In addition, the data does not indicate whether it was generated using day 20 or 21 cesareaned fetuses (assuming the day of a confirmed mating was day 0) which would affect the degree of skeletal ossification. In conclusion, this submission is inadequate to alter the decision of OPP's Health Effects Division, Developmental Peer Review Committee regarding the NOEL.