

The Toxicology Review has identified only one study that does not meet Agency requirements. The following information is needed for the rat teratology study:

Rat Teratology Study - (OMMAW)

7-15-85

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~~299-6503~~
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7/15/85

HISTORICAL CONTROL DATA FOR AAU NOTED MAJOR AND MINOR MALFORMATION, SKELETAL VARIATION FOR RATS STUDIED IN THE FANC LAB FROM 1982 THROUGH 1984.

SAMPLE: Study No. 682

<u>MAJOR MALFORMATION</u>	<u># FETUSES</u> <u># FETUSES EXAMINED</u>	<u># LITTERS OFFSPRING</u> <u># LITTERS EXAMINED</u>
- Acanthia etc.	3/60	1/20
<u>MINOR MALFORMATION</u>		
- Malformed Tail etc.	4/60	2/19
<u>SKELETAL VARIATION</u>		
- Wavy Ribs	6/60	3/20
- Missing & 5 sternum etc.	10/60	2/20

WE CANNOT BE MORE SPECIFIC BECAUSE THE PREVIOUS RAT TERATOLOGY STUDY HAD NO MAJOR MALFORMATIONS REPORTED; THE RAT REPRODUCTION HAS SEVERAL UNUSUAL TERATOGENIC RESPONSES (NO AXIAL OPENING, etc) AND THEREFORE PROVIDES SOME ~~AN~~ IMPEDIMENT FOR FURTHER EXAMINATION OF THE RAT TERATOLOGY STUDY. XX 453

IN ADDITION, IN ORDER TO ESTABLISH THE ADEQUATE WORKING RANGE OF THE TERATOLOGY SYSTEMS 166

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AND TECHNIQUES EMPLOYED BY FMC, "POSITIVE CONTROL" DATA ARE REQUESTED. THESE DATA SHOULD BE REPORTED IN THE SAME MANNER AS DISCUSSED PREVIOUSLY WITH IDENTIFICATION OF THE "TEST COMPOUND".

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