

Nominations from FDA's Center for Drug Evaluation and Research

Chloral Hydrate Study using the p53 hemizygous Mouse Model (CDER)

CDER is requesting a p53 hemizygous study using the hypnotic drug chloral hydrate. This information will be important to the Center in the evaluation of the NTP supported Chloral Hydrate studies currently ongoing at NCTR under the FDA-NIEHS IAG. In addition, it will add to the CDER and NTP database for p53 conducted studies and assist in the validation and acceptance of the p53 test in regulatory decision making process.