

TO: MEDICAL RESEARCH PROJECT NO. 9905-001

October 18, 1994

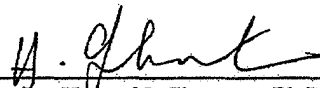
The original protocol is amended as follows:

1. Add the following to *Materials and Methods*, section E, *Diet Preparation and Analysis*: 'The contaminants, if any, in the sucrose to be used for this study were considered. Because the sucrose chosen for use was originally intended for human consumption, it was felt that any contaminants would be within acceptable ranges. However, the diet (containing sucrose) will be analyzed for lead content and the results from the analysis will be presented in the final report.' This addition, required by Good Laboratory Practices, was erroneously omitted from the original protocol.
2. The Haskell Sample Nos. assigned to the test substances were 20659, 20658, and 20202 for Fort Madison (FM), PLW-1, and Pb Acetate, respectively. The sample numbers for the two test soils were not available when the original protocol was written.
3. In *Materials and Methods*, section L, *Data Analysis*, it is erroneously stated that individual animal data as well as the mean for six animals in each group will be reported. This is changed to state that individual animal data as well as the mean for five animals in each group will be reported. The number of animals in each group was incorrectly stated in the original protocol.
4. The results of this study will be included in a final report written for Medical Research Projects (MRs) 9727, 9740, and 9905. These three projects were absolute bioavailability studies of soil lead in microswine; each project used different test soils. This change is made in order to present the results more efficiently and in a timelier manner.

Additional Information:

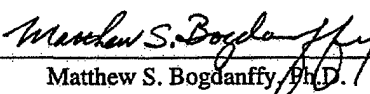
The intravenous dose of Pb Acetate administered in this study was intended to be used in comparison with the test soils labeled Fort Madison (FM) and PLW-1. The dosage of the Pb Acetate was calculated to be equivalent to the dosage of lead received by animals orally dosed with the lead-containing test soils. The intravenous dose of Pb Acetate used in MRs 9727 and 9740 were designed to accomplish a similar task; however, due to technical error, the Pb Acetate dose for MR 9740 was incorrectly prepared. The Pb Acetate dose group from MR 9727 will be used in comparison with the test soils in MR 9740. This information is being provided to explain why MRs 9727 and MR 9740 were sharing a Pb Acetate dose group, while MR 9905 was not.

Approved by:


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10/19/94
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