Exhibit 5

SECTION C

DESCRIPTION/SPECIFICATION/WORK STATEMENT

ARTICLE C.1. BACKGROUND

Precedents: Since 1980, NIEHS has supported a series of longitudinal studies of childhood lead poisoning. These studies have shown small deficits in the cognitive development of young children in association with levels of blood lead commonly found in the US. NIEHS has also supported clinical studies leading to the licensure of the drug succimer, an orally administered chelating drug now labelled for use in children with blood lead levels above 45 μg/dl, a level thought to indicate a high risk for symptomatic lead poisoning and above the levels that produce cognitive delay.

General Background: Cognitive delay in toddlers has been associated with maternal lead levels in the 10-20 μg/dl range, and delays in four year olds with similar lead concentrations when they themselves were 2 years old. The Centers for Disease Control and the American Academy of Pediatrics have revised downward the blood lead levels of concern in young children, and children with blood lead levels greater than 10 μg/dl are now thought to have unacceptable exposure to lead. There are, however, no data on whether treatment of children with chelating agents prevents the cognitive delay associated with these levels. There are about four million children who fulfill the new criteria for unacceptable exposure to lead. NIEHS believes that large numbers of children with blood lead levels below 45 μg/dl will be treated with succimer, and that a clinical trial of the use of succimer in the prevention of lead-associated cognitive delay in young children is both necessary and timely. The objective of this Contract is to conduct, analyze, and issue a report of a randomized, multi-center, placebo controlled trial of succimer in the prevention of lead-associated cognitive delay in young children. This Contract is for one (1) of three (3) or possibly four (4) Clinical Centers. A separate, companion contract, NO1-ES-35360 has been awarded for the support of the Coordinating Center.

ARTICLE C.2. STATEMENT OF WORK

a. Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the work set forth below, including recruitment, treatment, retention, and follow-up of children in a clinical trial. In doing so, the Contractor shall comply with all local, state, and Federal laws and regulations pertinent to the various aspects of the trial. The Contractor shall conduct performance predicated on the agreements and understandings reached through discussions and negotiations leading to award based on the following documents which are incorporated by reference:

(1) Original Proposal dated November 24, 1992
(2) Revised Proposal dated May 10, 1993

(3) Best and Final Offer dated June 4, 1993
(4) Clarifying Information dated June 13, 1993

If there is any inconsistency between the referenced documents and the work described in Paragraph a. of this ARTICLE, the terms and conditions of Paragraph a. of this ARTICLE shall control.

(BASIC CONTRACT)

The protocol and strategies for the trial will result from the deliberations of the Steering Committee during the planning phase. The Steering Committee, as initially constituted, shall consist of the PIs of the Clinical Centers, the PI of the Coordinating Center, and the NIEHS Project Officer. The PI of the central lab will be a member of the Steering Committee ex officio. The Manual of Operations and Final Protocol shall be incorporated by reference into this Statement of Work when they are completed by the Steering Committee and approved by the Data and Safety Monitoring Committee. The clean up protocol at each site will be incorporated by reference into this Statement of Work when completed by the Clinical Center PI and approved by the Project Officer. The Steering Committee may elect to alter its composition at any time after it has been constituted; it must notify the PO of plans to do so. The trial shall proceed as follows: 9-12 months for planning; about 1 year for patient enrollment and treatment; the remaining 3 years for follow-up. Each child will be followed to age 4 at a minimum; longer follow-up is desirable for those children randomized early. Most close out activities should be completed by the final (5th) year of the contract. The activities, none of which are currently anticipated, of any center beyond five years from the initial award except for work specified herein will depend on the issuance of a continuation RFP by the Institute and successful re-competition. The trial is of oral chelation therapy with the drug succimer in lead exposed children (blood leads of about 20 µg/dl to 45 µg/dl) of about 18 to 36 months of age. The endpoints are the scores on developmental tests; other endpoints of interest include evidence of drug efficacy and compliance, such as urine and blood lead levels; excretion of other ions like iron, zinc, and calcium; and nervous system, renal and hematopoietic function/toxicity.

The Clinical Center shall evaluate the children prior to randomization for iron, vitamin, or other nutrient deficiency, and treat such deficiencies. Clinical Center staff, as may be augmented by local/state health officials, shall evaluate children's homes, and, if necessary, their day care or other sites where they spend time, and provide clean-up according to trial protocol. The criteria by which homes will be evaluated and the clean-up protocol shall be decided during the planning phase, but clean-up will not be identical at each site, and will consist of means suited to the catchment area of each Clinical Center. The Steering Committee shall, among their other functions, appoint a Clean-Up subcommittee, whose function will be to coordinate the various clean-up activities. However, the ultimate decision about clean-up methods at each site rests with the PI of the site and the PO. Chelation challenge and XRF studies are separately budgeted options, which may be included at some of the Clinical Centers (see "Options"below.