NOTICE OF OPPORTUNITY FOR CLINICAL TRIAL COLLABORATION

TREATMENT OF TYPE 2 DIABETES IN PEDIATRIC POPULATION: CHILDREN AND ADOLESCENTS

SUMMARY: The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health (NIH) and the Department of Health and Human Services (DHHS) is seeking proposals from companies in the form of capability statements for Clinical Trials to provide

1) insulin,
2) statin,
3) ACE inhibitor,
4) equipment needed for the care of children with type 2 diabetes (including glucose meters and strips, syringes, lancets, urine ketone strips, concentrated glucose solution for performing oral glucose tolerance tests, topical anesthetic cream for blood drawing, automated blood pressure devices and cuffs, automated scales),
5) equipment required to measure the effects of lifestyle change (including mechanically breaked cycle ergometers, heart rate monitors and electronic metronomes for performing PWC, accelerometers, pedometers),
6) materials to create a "toolbox" to be utilized to enhance the ability of underprivileged children to attain lifestyle changes, particularly increased physical activity (including sneakers, jump ropes, etc.)

STUDY GOAL: The overall goal of this study is to evaluate potential treatment modalities for type 2 diabetes in children and adolescents, to determine the safest and most efficacious options for treatment. Twelve clinical centers will enroll a total of approximately 750 patients. For medical care, subjects will be seen every 2 months during the first year, and every 3 months during the subsequent years. The total duration of the trial is 5 years. The primary outcome will be related to the achievement and maintenance of glycemic control; numerous important secondary outcomes will also be evaluated, including preservation of beta cell function, side effects and quality of life, markers for vascular complications, and cost effectiveness.

Applicants for a Clinical Trial Agreement to support this clinical trial must include a description of the staff with experience and expertise to collaborate in multicenter clinical studies of patients with diabetes. Applicants should provide a detailed description of the materials or equipment to be provided. How the drug or product will be sent to each participating center, as well as packaging, storing and accountability issues must be presented.

CAPABILITY STATEMENTS: A selection committee will utilize the information provided in the "Collaborator Capability Statements" received in response to this announcement to help in its deliberations. It is the intention of the NIDDK that all qualified Collaborators have the opportunity to provide information to the selection committee through their capability statements. The Capability Statement should not exceed 10 pages and should address the following selection criteria:

1. The statement should provide specific details about the product to be supplied, particularly any validation of its use in a pediatric population, and in obese subjects, if relevant.
2. The statement should include a detailed plan demonstrating the ability to provide sufficient quantities of the product in a timely manner for the duration of the study.
3. The statement may include outcome measures of interest to the Collaborator.

DATES: Only written Clinical Trial capability statements received by the NIDDK on or before **August 11, 2003** will be considered. Applicants meeting the criteria as set forth in this announcement may be invited, at the Collaborator's expense, to discuss their plans, capabilities, and research findings pertinent to the study at a meeting of the Steering Committee, date and

place to be determined. The Institute may issue an additional notice of Clinical Trial opportunity. This notice is directed toward companies with resources to support collaborations.

FOR ADDITIONAL INFORMATION AND QUESTIONS: Capability statements should be submitted to Rochelle Blaustein, J.D., Director, Technology Transfer and Development, National Institute of Diabetes and Digestive and Kidney Diseases, 12 South Drive, MSC 5632, Bethesda, MD 20892-5632, rochelleb@intra.niddk.nih.gov, Fax: 301-402-7461. Scientific questions may be addressed to Dr. Barbara Linder at (301) 594-0021 or linderb@extra.niddk.nih.gov.