DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
The Tower Building
1101 Wootton Parkway, Suite 200
Rockville, Maryland 20852

Telephone: 240-453-8298
FAX: 240-453-6909
E-mail: patrick.mcneilly@hhs.gov

December 13, 2006

Sharon L. Tennstedt, Ph.D.
Vice President
Director, Center for Scientific Integrity
New England Research Institutes, Inc.
9 Galen Street
Watertown, MA 02472

RE: Human Research Subject Protections Under Federalwide Assurance FWA-297

Research Project:	**Health Effects of Dental Amalgams in Children**
Principal Investigator:	**Dr. Sonja M. McKinlay**
HHS Project Number:	**5U01DE011886**

Dear Dr. Tennstedt:

The Office for Human Research Protections (OHRP) has reviewed the New England Research Institute's (NERI) September 29, 2006 report that was submitted in response to OHRP's August 29, 2006 letter regarding the above-referenced research.

Based on its review of your August 29, 2006 and September 1, 2005 reports, OHRP makes the following determinations:

> It was alleged that the informed consent documents for the above-referenced research failed to provide an adequate description of the reasonably foreseeable risks and discomforts of the research, as required by Department of Health and Human Services regulations at 45 CFR 46.116(a)(2). In specific, it was alleged that the risks of dental amalgam were not adequately described in the informed consent document. OHRP finds that this allegation could not be substantiated. In particular, OHRP notes that the IRB-approved informed consent document stated:
>
> > (1) "Dental amalgam is the standard, most widely used filling for back teeth. It is a mixture of metals held together by mercury. Because mercury in large amounts

> can cause health problems, scientists have wondered whether the very small amounts of mercury from dental amalgam and even from food, water and air can also cause some of these problems. High levels of mercury can cause tremors, loss of memory, insomnia, fatigue, headaches, irritability, slowed nerve conduction, appetite loss, and kidney problems."
>
> (2) "Some temporary discomfort may happen after any of the above dental treatments. Local anesthesia to numb the teeth and gums (lidocaine, carbocaine) will always be used when indicated to prevent any discomfort."

As a result of the above determination, as well as those noted in OHRP's letter of August 29, 2006, OHRP finds that NERI has adequately addressed OHRP's questions and concerns. Therefore, there should be no need for further involvement of OHRP in this matter.

OHRP appreciates the continued commitment of your institution to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Patrick J. McNeilly, Ph.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Ms. Nancy Gee, IRB Administrator, NERI
Dr. Donald Brambilla, Chair, Institutional Review Board, NERI
Commissioner, FDA
Dr. Linda Tollefson, FDA
Dr. Norris Alderson, FDA
Dr. Sam Shekar, NIH
Dr. Bernard Schwetz, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael Carome, OHRP
Dr. Kristina Borror, OHRP
Dr. Irene Stith-Coleman, OHRP
Ms. Shirley Hicks, OHRP
Ms. Patricia El-Hinnawy, OHRP
Ms. Carla Brown, OHRP