DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

IND 105,457

George J. Schwartz, M.D.
Chief, Pediatric Nephrology
University of Rochester Medical Center
601 Elmwood Avenue, Box 777
Rochester, NY 14642

Dear Dr. Schwartz:

We acknowledge receipt of your Investigational New Drug Application (IND), submitted May 8, 2009, received May 12, 2008, under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Omnipaque 300 (iohexol) Injection.

After reviewing the information contained in your submission, we have concluded that your study meets all of the requirements for exemption from the IND regulations and, therefore, an IND is not required to conduct your investigation. In accordance with 21 CFR 312.2(b)(4) of the regulations, FDA will not accept your application.

The IND regulations [21 CFR 312.2(b)] state that clinical investigation of a drug product, including a biological product, that is lawfully marketed in the United States is exempt from the requirements for an IND if all of the following apply:

1. The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication for use, nor intended to be used to support any other significant change in the labeling for the drug.

2. The investigation is not intended to support a significant change in the advertising for a prescription drug product.

3. The investigation does not involve a change in route of administration, dosage level, or patient population, or other factor that significantly increases the risks (or decreases the acceptability of risks) associated with use of the drug product.

4. The investigation is conducted in compliance with the requirements for institutional review (21 CFR Part 56) and informed consent (21 CFR Part 50).

5. The investigation is conducted in compliance with the requirements of 21 CFR 312.7, i.e., the drug may not be represented as safe or effective for the purposes for which it is under investigation, nor may it be commercially distributed or sold.

In addition, 21 CFR 312.2(b)(5) exempts from the IND requirements a clinical investigation that involves use of a placebo if the investigation does not otherwise require submission of an IND.

We remind you that exemption from the requirements for an IND does not in any way exempt you from complying with the requirements for informed consent under 21 CFR 50.20 or from initial and continuing Institutional Review Board review under 21 CFR Part 56.

For additional information, you can check our web site at http://www.fda.gov/cder for the IND regulations.

Should you have any questions or wish to bring to our attention any information that would affect our evaluation, please contact:

Edward Fromm, R.Ph., RAC
Chief, Project Management Staff
(301) 796-1072

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Linked Applications	Sponsor Name	Drug Name / Subject
IND 105457	SCHWARTZ GEORGE J MD	OMNIPAQUE 300 (IOHEXOL)

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/s/

NORMAN L STOCKBRIDGE
05/29/2009