



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

IND 104,114

IND 104,116

Children's Hospital & Research Center Oakland
Attention: Caroline Hastings, MD
Director, Fellowship Program
747 52nd Street
Oakland, CA 94609-1809

Dear Dr. Hastings:

Please refer to your Investigational New Drug Application (IND) submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act for Trappsol Brand of Endotoxin Controlled Hydroxyl-Propyl-Beta-Cyclodextrin (HPBCD).

We also refer to the meeting we scheduled on February 26, 2009, in response to your January 26, 2009 meeting request. The purpose of the meeting was to discuss removal of your clinical hold for IND 104,114 and IND 104,116. We are cancelling this meeting because the INDs are no longer on hold; therefore there is no justification for the Type A meeting. If you wish to schedule another meeting, you must submit a new meeting request.

If you have any questions, call me at (301) 796-2137.

Sincerely,

{See appended electronic signature page}

Stacy Barley, R.N., M.S.N., M.H.A.
LCDR/USPHS
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Linked Applications	Sponsor Name	Drug Name / Subject
IND 104114	Caroline Hastings, M.D.	Trappsol Brand of Endoxin Controlled Hydroxyl-Propyl-Beta-Cyclodextrin (HPBCD)
IND 104116	Caroline Hastings, M.D.	Trappsol Brand of Endoxin Controlled Hydroxyl-Propyl-Beta-Cyclodextrin (HPBCD)

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/s/

STACY R BARLEY
02/20/2009