

TELEPHONE CONVERSATION RECORD	Date: April 18, 2005	Time: 11:00
Mail Control No.: 136330 Inspection No.: N/A	License No.: 06-30933-02	Docket No.: 030-36825
Persons Called: Diane Jakorsky,, M.D. VP and David Durkee, Consultant	Licensee: Pfizer New Haven CRU	Telephone No.: 860-686-1881
Person Calling: Steven Courtemanche/(610) 337-5075		
Subject: Clarification concerning IND licensed materials.		
<u>Summary:</u> I spoke with Dr. Jakorsky and Mr. Durkee concerning the IND authorizations in 35.100. Contrary to my statements in the March 21, 2005 Deficiency letter, after speaking with NRC management, I determined that amendments would not be needed for the addition of other IND protocols. As long as the protocols are covered under 10 CFR 35.100 for uptake, dilution and excretion studies, the license being issued would cover the studies and the licensed material. I thanked them for their patience in this matter.		
Action Required/Taken: Document for ADAMS		
Prepared by Steven Courtemanche	Date: April 18, 2005	