U.S. NUCLEAR REGULATORY COMMISSION

TELEPHONE CONVERSATION RECORD

Date: 1/30/2007

Time: 1:00 PM

Mail Control or Report No(s). 139972 License No(s). 07-03990-01 Docket No(s). 03003868

Name of Licensee:	Astrazeneca Pharmaceuticals LP
Name of Participant(s):	Scott C. Petlick, CIH, RSO Dennis Lawyer, NRC
Telephone No.	302-886-1083
Subject: (NOTE: This will be used as the Documents Title in ADAMS)	RAI, 10CFR33.17(a)(4) exemption request
Summary:	I discussed with Mr. Petlick, that the preferable method for IND (Investigational New Drug) distribution authorization for a broadscope license is discussed in Appendix U of NUREG-1556, Volume 12. In order to manufacture and distribute IND drugs, it discusses the preferred method is to be authorized by 10 CFR 32.72 and not exempted from 10 CFR 33. 17(a)(4). However, since the change in 10 CFR 35, it seems that another authorization may be possible. A technical assistance request is being drafted to review the method for this authorization. A TAR number has not been assigned at this time. Astrazeneca Pharmaceuticals could pursue authorization by 10 CFR 32.72 and if the company did not qualify for 10 CFR 32.72, they could seek exemption for that requirement as stated in Appendix U of NUREG-1556, Volume 12 or they could wait until the technical assistance request results were obtained. I asked Mr. Petlick to review Appendix U and discuss with his management to determine which method to pursue. On February 2, 2007, 8:45 AM, Mr. Petlick left me a message stating that they wanted to wait for the result of the technical assistance request.
Action Required:	File in records.

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Prepared & SUNSI Review Completed By:	Dennis Lawyer	/ RA /	Date:	2/5/2007