CONVERSATION RECORD (time) (date) | TIME | DATE 12/1/09

VISIT ○ CONFERENCE TELEPHONE X

○ INCOMING
X OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT	ORGANIZATION (OFFICE, DEPT.ETC.)	TELEPHONE NO.
Duane White	NRC	301-415-6272

SUBJECT

C/N 318365 (New Appl. from Cardinal Health)

SUMMARY

This was a follow-up call after a discussion with Will Regits of Cardinal Health regarding their application for a new accelerator production license and my deficiency letter dated 10/20/09.

Mr. Regits had called to discuss the deficiency letter and questioned why they would be required to also apply for a new nuclear pharmacy license. He indicated that F-18 labeled FGD is produced at the accelerator facility located on the MSU campus and shipped to a Cardinal Health pharmacy for preparation of unit doses and commercial distribution to end users. He also stated that Cardinal Health will not engage in preparing unit doses at the accelerator facility or commercial distribution of FDG from the accelerator facility, therefore they do not see the need for a nuc. pharmacy license.

I agreed with Mr. Regits but contacted Duane White (NRC Headquarters office) for his opinion. Mr. White agreed that since Cardinal Health will not be preparing unit doses at the accelerator facility and will not be engaged in commercial distribution of product they would not need a nuc. pharmacy license. We also discussed another option: If Cardinal Health wanted to distribute FDG product commercially to pharmacies other than Cardinal Health or to end users, they could also apply for a manufacturing and distribution license. This would be in addition to applying for their accelerator production license.

After consideration, Cardinal Health has decided to apply for a new M&D license that would allow them to manufacture and distribute FDG to companies other than Cardinal Health (similar to Mallinckrodt 030-00001).

Mr. Regits decided to void C/N 318365 (application for an accelerator production license) and they will resubmit this application at the same time as their M&D application.

Since they are in the State of Michigan, they have until August 2010 (12 months from waiver termination for Michigan for NARM) to submit their new application for the M&D. Their initial application for the new production license was submitted well before August 2010 (it was submitted on June 24, 2009), but will be resubmitted at the same time as their application for a new M&D.

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
Kevin Null	Kevin D. Null	12/2/09

ACTION TAKEN

SIGNATURE TITLE DATE