From:	Elliott, Robin
To:	Jim Fongheiser (jgfong@aol.com); debbief@cardiocppa.com
Subject:	Request for additional information License No. 07-30713-01, CN 593063
Date:	Monday, March 13, 2017 2:51:00 PM

License No.: 07-30713-01
Docket No: 030-35921
Control No: 593063

Licensee Name: Cardiology Physicians, P.A.

Dear Dr. Pastore:

This refers to your request to amend your license dated February 3, 2017. In order to continue our review of your request, the following additional information is needed:

1. You requested I-123 be added for cardiac imaging studies. Please confirm that the studies being performed are diagnostic and not therapeutic studies.
2. Confirm that the material will be used in the facilities previously approved and no new facilities will be utilized for the study.
3. As per 10 CFR 35.6, please confirm that the study you are participating in is has the approval of an Institutional Review Board as defined by the Federal Policy for the Protection of Human Subjects. Provide information on the members of this committee; e.g., names, titles, degrees, contact information and their institutional affiliation.
4. Please confirm that you are obtaining "informed consent," from the human research subject as defined and described in the Federal Policy.
5. Please indicate whether the clinical study involves the licensed material to evaluate an investigational drug or whether the licensed material is integral to the study; i.e. is the drug being investigated.
6. If the licensed material is integral to the study, please provide the following:
    a. Indicate whether the material is an Investigational New Drug (IND) with FDA approval. If it is not, please indicate whether the drug is being administered under the oversight of a Radioactive Drug Research Committee (RDRC) approved by FDA. If so, provide information on the members of this committee; e.g., names, titles, degrees, contact information and their institutional affiliation.
    b. Relative to RDRC research:
        i. Briefly describe the review process for the research protocol design.
        ii. What is the selection process for research subjects?
        iii. Provide the criteria established for reporting events to the RDRC.
7. Please state whether the study will involve patients or volunteers. If volunteers are used, please address the following:
    a. What dose will they be receiving and how is the dose being determined?
    b. Please confirm that volunteers released from the study will not pose an exposure risk to the public in excess of the limits in 10 CFR 20.1301.

Your reply must be an originally signed and dated letter. The letter may be scanned and submitted as a pdf document attached to an email; or it may be transmitted by facsimile to (610) 337-5269; or it may be sent by regular mail. If we do not receive a reply from you within 30 calendar days from the date of this e-mail, we will assume that you do not wish to pursue your amendment request.

REC'D IN LAT 03/23/2017

Please respond by e-mail to acknowledge that you have received the e-mail request for additional information.

Regards,

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