

From: William Ward
To: Desrosiers-Clarke, Carolyne
Date: 10/25/01 11:57AM
Subject: RE: Request for additional information regarding your Pd-1 sourceapplication

Ms Desrosiers-Clarke,

Yesterday, I emailed you the WordPerfect file of questions I had when reviewing your application. I received your reply and am confident that the email process is working. While I was reviewing your application, the second reviewer was performing a simultaneous review and has generated several additional questions. I have added those questions in a WordPerfect file to this email. Please answer those questions as well. We will review your answers, and if we have no further questions, issue the certificate promptly.

Please respond to these question via letter, email or fax. Our fax number is (301) 415-5369. If you have any questions, you may phone me at the number provided below. Thank you very much.

Sincerely,

William R. Ward, P.E.
WRW1@NRC.GOV
NRC/NMSS/IMNS/MSIB
(301) 415-7038
m/s T8-F5

CC: John Jankovich; Seung Lee

2nd Round of Questions for DraxImage, Inc. concerning their Pd-1 source application

1. In your application review checklist, you checked "The applicant is manufacturer and distributor" row. In my email of 10/24/01, I discussed the need for a US distributor. Please confirm who is the manufacturer, who is the distributor and who the NRC would inspect and take enforcement action against should NRC regulations be violated.
2. In Section 3.1 of your application, you stated that "Figure 2 on page 6 is a micrograph..." Figure 2 shows the labeling. No copy of the micrograph(s) was provided in the application. Please provide a copy of the micrographs mentioned in section 3.1.
3. In Section 3 of your application, you stated that aluminum spacers may be substituted for titanium spacers. Have you performed an analysis of the effect of the use of the various materials (titanium tubing, aluminum spacer, platinum/iridium marker) used and the potential for corrosion between them? What were the results of that analysis?
4. In Section 3.5.2, what is the applying force used to close the end caps?
5. In Section 4, Labeling: The outer container label should provide the source model number, not isotope name in the statement of "The U.S. Nuclear Regulatory Commission has approved distribution of BrachySeedPd-103..." The LS-1 label was correct in this regard.
6. In my questions provided on 10/24/01, I asked about the durability of the labels. In order to clarify that question, we are asking the following. What are the label's material, size, and how is the labeling wording added (etched, engraved on metal)? Please note that the label and wording must be legible and durable.
7. In Section 6, page 14, Figure 4 states, "BrachySeed™ Pd-103 (DraxImage model LS-1) Photon Spectrum." Please clarify this figure, is it for the Pd-103, or I-125, and what significance does it have to your application?
8. In Appendix 6, Quality Manual, section 2.2, how often are internal audits and supplier/contractor audits performed?
9. In Appendix 6, Quality Manual, section 8.1, what fraction of your raw materials and finished products are tested? If not 100%, how do you decide what is tested?

NOTE TO FILE FOR SSD CASE NR-1121-S-102-S

This email was sent to DraxImage. However, by the time I entered it into ADAMS, the outgoing message had been deleted from my GroupWise folders. I only have a hardcopy of the email and attachment, but am unable to printout the properties page we normally include with an email in ADAMS. Later responses from DraxImage demonstrate that the email was received and understood by them.

A handwritten signature in black ink, appearing to read "William R. Ward". The signature is fluid and cursive, with a large loop at the end of the last name.

William R. Ward
2/5/2002