

From: William Ward
To: internet:CDesrosiers@DraxImage.com
Date: 10/24/01 4:56PM
Subject: Request for additional information regarding your Pd-1 source application

Ms. Desrosiers,

Thank you for returning my call earlier today. As I mentioned then, we have several questions concerning the application for the BrachySeed TM model Pd-1 source. I have attached in WordPerfect format, a listing which includes eight questions. These are essentially the same questions I discussed with you by phone earlier today. There is one question which is new, and that is question number 2 concerning the labels.

We cannot inspect manufacturing facilities outside of the US, nor can we adequately enforce our regulations outside of the US. Therefore, we require that foreign manufacturers have a US based distributor. As we discussed, AAC Consulting Group is listed as the distributor of your products in the US. Our regulations and guidance require that the address of the distributor in the United States be listed on the labels of products distributed in the United States. Currently, the labels you provided in Section 4 of your application list DraxImage, Inc. in Canada. We cannot approve the distribution of a source in the US without the US distributor's address appearing on the label.

We realize that the previously issued SSD Certificate of Registration, NR-1121-S-101-S for the LS-1 iodine-125 source also showed labels with DraxImage, Inc. in Canada. It was an oversight on our part to accept the labels without the US distributor listed on them. In our phone conversation earlier today, you mentioned you were considering amending this registration certificate to include 'sterile' product labels as well as the 'non-sterile' labels. If this is the case, we would request that you amend both sets of labels for the LS-1 at that time, and we would correct that certificate at that time.

Please reply and let me know that you received this email and that you were able to read the attached WordPerfect file. Please respond to these questions 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

Questions for DraxImage, Inc. concerning their Pd-1 source application

1. Two different summary data sheets were submitted, one with the letter has a Rockville address for AAC Consulting Group. The one in the notebook has the same Bethesda address that certificate NR-1121-S-101-S has, except that the suite number is now 850, vice 800 as on that certificate. Which address is correct?
2. For devices marketed in the United States, we must have the U.S. address on the labels. The labels you provided in Section 4 of your application for the Pd-103 list DraxImage, Inc. in Canada. These labels must have the address for the U.S. distributor, as listed on the certificate on the label. Please change the labels to show the U.S. distributor name.

NOTE: We realize that the SSD Certificate of Registration previously issued to you, NR-1121-S-101-S, for the LS-1 model iodine-125 seeds, had labels with DraxImage, Inc. in Canada on them. Accepting the labels without the U.S. distributor name on them was an oversight on our part. We will contact you separately about correcting this situation.

3. Section 2 - Conditions of Use, and Section 5, Prototype Testing, state classification is ISO/98/C53211. Appendix 3, section 1 states it is ISO/99/C53211. Date of standard is 1999. Please confirm that first classification is a typographical error and that the second classification is correct.
4. Label material description was not specified. The April 12, 2000 Request for Additional Information for the LS-1 source, question 8, asked whether the label material would be durable. The response did not clearly state the durability. NR-1121-S-101-S stated labels would be legible and made of durable material for the LS-1. Please describe the label's durability.
5. Appendix 3, Sections 1.0, 2.0, and 2.4, mention ISO 2929:1999(E) as the standard. Please confirm that this is a typographical error in referencing ISO 2919:1999(E).
6. Package Insert isodose contour plot does not have units specified. The units are specified in Section 6, Radiation Profiles, Figure 5a. Please specify units on the package insert.
7. Basis for Radiation Profile calculations not specified. Please specify how the calculations given in Section 6, Radiation Profiles, paragraph 6.3, were determined. Also, would the concerns regarding hospital personnel exposures due to implantation and removal of these Pd-103 sources be the same as those discussed in the correspondence for the LS-1 iodine-125 source?
8. Section 7, Quality Control, Page 17 discusses counting the iodine-125 removed from the source. This appears to be a copy of your BrachySeed™ iodine-125 application which has not been updated for the Pd-103 source. Please provide a new page 17 which correctly identifies the radioisotope being counted as Pd-103.

From: "Desrosiers-Clarke, Carolyne" <cdesrosiers@draximage.com>
To: "William Ward" <WRW1@nrc.gov>
Date: 10/24/01 5:28PM
Subject: RE: Request for additional information regarding your Pd-1 sourceapplication

Mr. Ward,

This is to confirm that we have indeed received your questions and plan to respond to them tomorrow with the hope of getting final approval of this submission next week.

Thank you for the timely attention you have demonstrated in this matter.

Regards,
Carolyne

-----Original Message-----

From: William Ward [mailto:WRW1@nrc.gov]
Sent: Wednesday, October 24, 2001 4:56 PM
To: CDesrosiers@DraxImage.com
Cc: John Jankovich; Seung Lee
Subject: Request for additional information regarding your Pd-1 source application

Ms. Desrosiers,

Thank you for returning my call earlier today. As I mentioned then, we have several questions concerning the application for the BrachySeed TM model Pd-1 source. I have attached in WordPerfect format, a listing which includes eight questions. These are essentially the same questions I discussed with you by phone earlier today. There is one question which is new, and that is question number 2 concerning the labels.

We cannot inspect manufacturing facilities outside of the US, nor can we adequately enforce our regulations outside of the US. Therefore, we require that foreign manufacturers have a US based distributor. As we discussed, AAC Consulting Group is listed as the distributor of your products in the US. Our regulations and guidance require that the address of the distributor in the United States be listed on the labels of products distributed in the United States. Currently, the labels you provided in Section 4 of your application list DraxImage, Inc. in Canada. We cannot approve the distribution of a source in the US without the US distributor's address appearing on the label.

We realize that the previously issued SSD Certificate of Registration, NR-1121-S-101-S for the LS-1 iodine-125 source also showed labels with DraxImage, Inc. in Canada. It was an oversight on our part to accept the labels without the US distributor listed on them. In our phone conversation earlier today, you mentioned you were considering amending this registration certificate to include 'sterile' product labels as well as the 'non-sterile' labels. If this is the case, we would request that you amend both sets of labels for the LS-1 at that time, and we would correct that certificate at that time.

Please reply and let me know that you received this email and that you were

able to read the attached WordPerfect file. 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: "Flanagan, Richard" <rflanagan@draximage.com>

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 (one is included)from DraxImage demonstrate that the email was received and understood by them.



William R. Ward
2/5/2002