

From: Elizabeth Ullrich
Sent: Tuesday, February 24, 2009 2:13 PM
To: robertj.parker@fda.hhs.gov
Subject: amendment letter dated January 26, 2009

License No. 19-07538-05
Docket No. 030-31689
Control No. 143266

Memo to: Robert Parker, PhD, Acting Director, Laboratory of Clinical Pharmacology, US FDA, DHHS

From: Betsy Ullrich, Senior Health Physicist, US NRC, Region I Office

Please provide additional information about the training and experience of Donna Volpe, in order for us to approve her as an authorized user under your license. The information should include a brief resume of her training and experience, and should include the type (on-the-job or formal course work), location, and duration of the training. Training should cover (a) principles and practices of radiation protection, (b) radioactivity measurements, standardization, and monitoring techniques and instruments, (c) mathematics and calculations basic to the use and measurement of radioactivity, and (d) biological effects of radiation. The description of her experience with the use of licensed materials should include the specific isotopes handled, the maximum quantities of materials handled, where the experience was gained, the duration of experience, and the type of use.

Please note that you may not reply to this memo by return e-mail. Your reply must be in writing by letter or facsimile (610-337-5269). 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 application.

If you have any questions, please contact me (contact information listed below). Thanks,
Betsy

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E-mail Properties

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Subject: amendment letter dated January 26, 2009

Sent Date: 2/24/2009 2:02:06 PM

Received Date: 2/24/2009 2:13:00 PM

From: Elizabeth Ullrich

Created By: Elizabeth.Ullrich@nrc.gov

Recipients:

robertj.parker@fda.hhs.gov (robertj.parker@fda.hhs.gov)

Tracking Status: None

Post Office:

Files Size Date & Time

MESSAGE 9091 2/24/2009

Options

Expiration Date:

Priority: olImportanceNormal

ReplyRequested: False

Return Notification: False

Sensitivity: olNormal

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