



CardinalHealth

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August 5, 2019

Cassandra Frazier
U.S. Nuclear Regulatory Commission
Region III – Division of Nuclear Materials Safety
2443 Warrenville Rd, Suite 210
Lisle, IL 60532-4352

Re: Amendment Request for Radioactive Materials License 34-29200-01MD, Cardinal Health, Dublin, OH.

Licensing / Ms. Frazier:

Cardinal Health 414, LLC (hereafter Cardinal Health) received a previous amendment based on our request dated April 5, 2010 for adding 5 millicuries of Radium-223 for distribution to authorized recipients for a single location. General information for the radiochemical development and the use in clinical trials or medical use of Radium-223 dichloride was initially included. Since that time, U.S. FDA has approved Ra-223 dichloride for medical use under 10 CFR 35.300; and Cardinal Health has received licenses specifically for manufacturing and preparation or distribution of Ra-223 under Cardinal Health NRC licenses: 34-32780-04MD and 34-31473-03MD, respectively.

The renewal application for the above referenced license dated July 20, 2011 included Ra-223, total 5 millicuries for distribution in any form for all licensed locations as indicated in items 6.J – 9.J. Cardinal Health now requests the authorized use of 5 millicuries (185 MBq) Radium-223 for re-distribution only (as a pass through) to authorized recipients with no change to the manufacturer's and dispensing pharmacies' labeling, packaging or shielding as indicated in items 6.J. – 9.J. for all locations.

In addition, please change the atomic number range in item item 6.A. from 1 through 83, to 1 through 90 with half life less than 120 days, which would include all nuclides in equilibrium for isotopes of Ra-223 and Ac-227.

Also, please change the atomic number range in item 6.N. from 1 through 83, to 1 through 90 for analytical wipe samples to measure and monitor the package removable contamination for all nuclides permitted by this license, if necessary.

August 5, 2019

If you have any questions regarding this request, please contact me at 614.757.9586.

Sincerely,



Glenn Sullivan
Corporate Radiation Safety Officer
Director, Health Physics
Nuclear & Precision Health Solutions

/dh

cc Laura Upchurch, RSO, Loc. 7002
Melissa George, RSO, Loc. 7010
Phillip Heim, RSO, Loc. 7011
Joshua Pruitt, RSO, Loc. 7013
Christie Holland, RSO, Loc. 7016
William Balogh, RSO, Loc. 7025
Frederick White II, RSO, Loc. 7028
Earl Robertson, RSO, Loc. 7030
Jay Simmons, RSO, Loc. 7088
Brian Porter, RSO, Loc. 7109
Dane Dishman, RSO, Loc. 7120
John A. Miller, RSO, Loc. 7128
Bobby Barlett, RSO, Loc. 7172
Mark Peters, RSO, Loc. 7200
Nate Johnson, RSO, Loc. 7201
Thomas Sundrla, Loc. 7231
Cynthia Martin, RSO, Loc. 7232
Micah Rydman, RSO, Loc. 7306
David Webb, RSO, Loc. 7341
Justin Goodnite, RSO, Loc. 7545

Consolidated NRC License File (3)

Song, Taehoon

From: Hill, Dan <dan.hill@cardinalhealth.com>
Sent: Friday, August 02, 2019 1:53 PM
To: Frazier, Cassandra
Cc: Parker, Bryan
Subject: [External_Sender] 34-29200-01MD request docket 030-36973
Attachments: 190805 Add Ra223 redistribution NRC 34-29200-01MD.pdf

Sandy or Bryan,
Please see the attached request from Cardinal Health 414, LLC.
You may choose to combine this with other license actions pending for NRC license 34-29200-01MD.

If you have any questions please contact Glenn Sullivan 614.757.9586.
Also, if a hard copy is needed please advise.
Thank you.

Dan

Dan Hill
Quality and Regulatory
Nuclear & Precision Health Solutions
CardinalHealth
614.757.5074 office
614.652.4598 fax

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

From: copycenter@cardinalhealth.com <copycenter@cardinalhealth.com>
Sent: Friday, August 2, 2019 9:34 AM
To: Hill, Dan <dan.hill@cardinalhealth.com>
Subject: Message from "RNP002673616C91"

This E-mail was sent from "RNP002673616C91" (MP C6502).

Scan Date: 08.02.2019 09:33:58 (-0400)
Queries to: copycenter@cardinalhealth.com

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Svenska: <http://www.cardinalhealth.com/en/support/terms-and-conditions-english.html>

Song, Taehoon

From: Tomczak, Tammy
Sent: Tuesday, August 06, 2019 1:57 PM
To: Song, Taehoon; Pavon, Sandy
Cc: Parker, Bryan
Subject: FW: Need to open an action
Attachments: [External_Sender] 34-29200-01MD request docket 030-36973

Hi Sandy and Tae,

Can you please add the attached to ADAMS?

Thanks,
Tammy

From: Parker, Bryan
Sent: Tuesday, August 06, 2019 1:52 PM
To: Tomczak, Tammy <Tammy.Tomczak@nrc.gov>
Subject: Need to open an action

Hey Tammy,

We need to process in the attached as an amendment request. Having recently completed CN612142 (which you are probably processing for mailout today-ish), this would NOT be combined with that.

I don't believe a hard-copy is coming in (he mentioned it in his e-mail, but I did not request one)

Let me know if there are questions.

Thanks.
Bryan

Bryan A. Parker
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