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U.S. Pharmaceuticals
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February 25, 2014

U.S. Nuclear Regulatory Commission
Region I
Suite 100
2100 Renaissance Boulevard
King of Prussia, PA 19406

Attn: Betsy Ullrich
Docket No. 030-29266
Control No. 582936

Re: Name Changes Request (License No. 06-27843-02)

The purpose of this letter is to provide the information as requested to support the qualifications of Richard Burrell and David Harden. We are also requesting the removal of specific radioisotopes from our site license as listed toward the bottom.

Rich Burrell:

- Worked safely with radioisotopes at BMS for the past 11 years.
- During the first year of BMS career was mentored by senior group member Samuel Bonacorsi on the safe usage of long-lived isotopes.
- More recently was mentored by senior group member Doug Dischino on the safe usage of short-lived isotopes.
- Continue to work with senior group member David Donnelly (Lawrenceville, NJ site) to gain additional experience with short-lived isotopes.
- Has attended the BMS initial radiation safety training as well as annual refresher training.
- Best practices to safely handle and minimize exposure to low energy beta emitters like tritium and carbon-14 and higher energy positron/gamma emitters like fluorine-18 and copper-64.
- Techniques for avoiding exposure to radioactivity, the ALARA principles were the foundation of the training.
- Use of shielding, ways to shorten exposure time and ways to increase the distance from radioactivity were always considered.
- Monitored personal exposure to radioactivity using dosimetry techniques such as film badges, electronic dosimeters and urinalysis.
- Used area monitoring techniques in the laboratory such as Geiger counters, liquid scintillation counters and gamma counters.
- Routinely measured the specific activity of synthesized samples and calculated the total activity in the sample. Used the isotope half-life to calculate the amount of activity remaining at a given time. Calculated the thickness of lead shielding needed to safely work with a specific quantity of fluorine-18.

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Converted between units of radioactivity such as Becquerel and curie. Converted between units of absorbed dose such as rad and gray. Converted between units of dose equivalent such as rem and sievert.

- All of the experience described above was gained over the past 11 years at BMS. During that time position at BMS has required synthesis of isotopically labeled pharmaceuticals.
- Rich Burrell has also been responsible for supervising and mentoring other members of the radiochemistry group that handle radioisotopes. Rich has worked with many curies of radioactive materials during his career at BMS. The maximum amount of a single isotope that he has used at a given time is: 1 Ci of tritium (NJ site), 400 mCi of carbon-14 and 500 mCi of fluorine-18.

Requesting Rich Burrell to be authorized to use: H-3, C-14, F-18, Cu-64, Ge-68, Ga-68, Ca-45 and Cs-137

David Harden:

- Has attended the BMS initial radiation safety training as well as yearly refreshers starting in 1997 to present.
- On a project by project basis used "mathematics and calculations" to convert specific activity to molarity incorporating ½ life decay.
- Worked with and supervised large scale screening projects (>1 million data points per project) that have utilized 3H, 14C, I-125, and P-33. In 2014 has one active project with 3H, that included both biochemical (enzymatic), cell based, and cell membrane based assays. These have included the use of liquid scintillant in 96 well micro titer plates to most recent Scintillation Proximity Assay (bead based) 1536 well plate- based assays. Radioligands have originated from external commercial vendors as well as in house prepared labeled small molecules.
- All of his experience (17 years) is here with BMS. He did not use radioactivity in previous jobs.
- Isotope quantities have ranged from several 100's of mCi on hand to 50 uCi.
- Also note, actively participated in regularly scheduled monitoring for contamination of the mega labs.

Requesting Dave Harden to be authorized to use: H-3, C-14, P-32, P-33, S-35, Ca-45, I-125 and Cs-137.

Additionally we would like to remove the following isotopes from our license: Chromium 51, Indium 111, Iodine 123, Iodine 131 and Zirconium 89.

Please contact me if you have any questions or concerns regarding this request.

Sincerely,

Erich R. Salomon
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