## **FAX TRANSMISSION FORM**



Eagleview Corporate Center 665 Stockton Drive Exton, PA 19341 Phone: 610.458.6985

ax: 610.458.8258

## CONFIDENTIAL INFORMATION

THE INFORMATION CONTAINED IN THIS FACSIMILE MESSAGE IS LEGALLY PRIVILEGED AND CONFIDENTIAL INFORMATION INTENDED ONLY FOR THE USE OF THE INDIVIDUAL OR ENTITY NAMED BELOW. IF THE READER OF THIS MESSAGE IS NOT THE INTENDED RECIPIENT, YOU ARE HEREBY NOTIFIED THAT ANY DISSEMINATION, DISTRIBUTION OR COPY OF THIS FAX IS STRICTLY PROHIBITED. IF YOU HAVE RECEIVED THIS FAX IN ERROR, PLEASE IMMEDIATELY NOTIFY US BY TELEPHONE AND RETURN THE ORIGINAL MESSAGE TO US AT THE ADDRESS ABOVE VIA THE UNITED STATES POSTAL SERVICE. THANK YOU.

TO:

**Brian Parker** 

**COMPANY:** 

NRC

FAX:

404-562-4955

FROM:

Jason Van Buren

DATE:

04-01-05

Number of Pages:

6

(including cover page)

Message:

Per your request, the following in our Information regarding the acquisition of 3-Dimensional Pharmaceuticals, Inc. by Johnson & Johnson and also the reassignment of our Radiation Safety Officer.

136441



Eagleview Corporate Center 665 Stockton Drive Exton, PA 19341

Telephone:

(610) 458-8959

Fax:

(610) 458-5690

April 1, 2005

U. S. Nuclear Regulatory Commission

Attn: Mr. Brian Parker

Subject: Name Change

3-Dimensional Pharmaceuticals, Inc.

License # 37-30182-01

## Dear Mr. Parker:

Per your request and in accordance with 10 CFR 30.34(b) this memo is providing notification that 3-Dimensional Pharmaceuticals Inc. has been acquired by Johnson and Johnson as of March 28, 2003. I request an amendment to item two (2) of NRC Form 313 in order to change the company name to Johnson and Johnson Pharmaceutical and Development LLC.(JNJPRD). The location and type of program will not be changing as described in Attachment 1. However, a request to reassign Kevin Turner as the Radiation Safety Officer has been submitted.

Should you have any questions, please give me a call at (610) 458-6985.

Jason Van Buren

Senior Director, Operations, East

Radiation Safety Officer

Attachment 1: Information Needed for Change of Ownership



**Eagleview Corporate Center** 665 Stockton Drive Exton, PA 19341

Telephone: (610) 458-8959

Fax:

(610) 458-5690

April 1, 2005

U. S. Nuclear Regulatory Commission

Attn: Mr. Brian Parker

Subject:

Name Change

3-Dimensional Pharmaceuticals, Inc.

License # 37-30182-01

Dear Mr. Parker:

Per your request and in accordance with 10 CFR 30.34(b) this memo is providing notification that 3-Dimensional Pharmaceuticals Inc. has been acquired by Johnson and Johnson as of March 28, 2003. I request an amendment to item two (2) of NRC Form 313 in order to change the company name to Johnson and Johnson Pharmaceutical and Development LLC.(JNJPRD). The location and type of program will not be changing as described in Attachment 1. However, a request to reassign Kevin Turner as the Radiation Safety Officer has been submitted.

Should you have any questions, please give me a call at (610) 458-6985.

Jason Van Buren Senior Director, Operations, East Radiation Safety Officer

Attachment 1: Information Needed for Change of Ownership

## Attachment 1: Information Needed for Change of Ownership

The following information was adopted from NUREG - 1556 Volume 7, Appendix E.

The applicant should provide the following information concerning changes of ownership or control by the applicant (transferor and/or transferee, as appropriate):

1. The new name of the licensed organization. If there is no change, the licensee should so state.

Johnson and Johnson. Pharmaceutical Research and Development, LLC

2. The new licensee contact and telephone number(s) to facilitate communications.

Kevin Turner, (w) 610-458-8959, (cell) 267-847-5994

3. Any changes in personnel having control over licensed activities (e.g., officers of a corporation) and any changes in personnel named in the license such as radiation safety officer, authorized users, or any other persons identified in previous license applications as responsible for radiation safety or use of licensed material. The licensee should include information concerning the qualifications, training, and responsibilities of new individuals.

Yes, Kevin Turner

4. An indication of whether the transferor will remain in non-licensed business without the license.

Research activities will remain the same after the transfer.

5. A complete, clear description of the transaction, including any transfer of stocks or assets, mergers, etc., so that legal counsel is able, when necessary, to differentiate between name changes and changes of ownership.

No change

6. A complete description of any planned changes in organization, location, facility, equipment, or procedures (i.e., changes in operating or emergency procedures).

No change.

 A detailed description of any changes in the use, possession, location or storage of the licensed materials.

No change in isotope usage, possession limits or storage.

8. Any changes in organization, location, facilities, equipment, procedures, or personnel that would require a license amendment even without the change of ownership.

No change.

An indication of whether all surveillance items and records (e.g., calibrations, leak tests, surveys, inventories, and accountability requirements) will be current at the time of transfer. A description of the status of all surveillance requirements and records should also be provided.

All surveillance records are up to date. Facility wipes are conducted by Environment Health and Safety (EHS) Department quarterly. An inventory of isotopes in the facility is conducted each quarter. Survey equipment is calibrated on an annual basis.

10. Confirmation that all records concerning the safe and effective decommissioning of the facility, pursuant to 10 CFR 30.35(g), 40.36(f), 70.25(g), and 72.30(d); public dose; and waste disposal by release to sewers, incineration, radioactive material spills, and on-site burials have been transferred to the new licensee, if licensed activities will continue at the same location, or to the NRC for license terminations.

No change. Decommissioning of facilities will not occur. Johnson and Johnson to accept facilities and license "As Is."

11. A description of the status of the facility. Specifically, the presence or absence of contamination should be documented. If contamination is present, will decontamination occur before transfer? If not, does the successor company agree to assume full liability for the decontamination of the facility or site?

There is no contamination or spill of radioactive materials in the facility as determined by the facility wipes. Removable contamination on surfaces (e.g. floors, walls, and bench tops) in excess of 200 dpm/100 cm<sup>2</sup> or inside equipment (e.g. centrifuge) in excess of 1000 dpm/100 cm<sup>2</sup> requires decontamination and resurvey of area(s). The RSO is notified in the event contamination levels exceed 2000 dpm/100 cm<sup>2</sup>.

12. A description of any decontamination plans, including financial assurance arrangements of the transferee, as specified in 10 CFR 30.35, 40.36, and 70.25. This should include information about how the transferee and transferor propose to divide the transferor's assets, and responsibility for any cleanup needed at the time of transfer.

The facility will not be decommissioned. Johnson and Johnson to accept the facility and license "As Is".

13. Confirmation that the transferee agrees to abide by all commitments and representations previously made to NRC by the transferor. These include, but are not limited to: maintaining decommissioning records required by 10 CFR 30.35(g); implementing decontamination activities and decommissioning of the site; and completing corrective actions for open inspection items and enforcement actions.

3-DP license to remain intact, name change only. Existing license conditions/requirements to remain in effect.

With regard to contamination of facilities and equipment, the transferee should confirm, in writing, that it accepts full liability for the site, and should provide evidence of adequate resources to fund decommissioning; or the transferor should provide a commitment to decontaminate the facility before change of control or ownership.

No Change

With regard to open inspection items, etc., the transferee should confirm, in writing, that it accepts full responsibility for open inspection items and/or any resulting enforcement actions; or the transferee proposes alternative measures for meeting the requirements; or the transferor provides a commitment to close out all such actions with NRC before license transfer.

There are no outstanding NRC inspection items.

14. Documentation that the transferor and transferee agree to the change in ownership or control of the licensed material and activity, and the conditions of transfer; and the transferee is made aware of all open inspection items and its responsibility for possible resulting enforcement actions.

No change

15. A commitment by the transferee to abide by all constraints, conditions, requirements, representations, and commitments identified in the existing license. If not, the transferee must provide a description of its program, to ensure compliance with the license and regulations.

Johnson and Johnson will accept and abide by all conditions/requirements stated in the 3DP license.