Kimberly-Clark

23 February 2010

Richard K. Struckmeyer
Licensing Branch
Division of Materials Safety and State Agreements
Office of Federal and State Materials and Environmental Management Programs
U.S Nuclear Regulatory Commission
One White Flint North
11555 Rockville Pike
Rockville, MD 20852-2738

Dear Mr. Struckmeyer,

In response to your email dated February 2, 2010 concerning Kimberly-Clark license 43-23865-01E, I submit the following information.

(1) A response to questions taken from NUREG-1556, Volume 15, Appendix F: "Faxable Version of Information Needed for Transfer of Control Application," follows:

1. Provide a complete description of the transaction (transfer of stocks or assets, or merger). Indicate whether the name has changed and include the new name. Include the name and telephone number of a licensee contact who NRC may contact if more information is needed.
    a. Please see the letter dated December 13, 1999 which is incorporated as a "Condition" in the license. This letter describes the acquisition of Ballard Medical Products (BMP) by Kimberly-Clark Corporation (KCC) including the purchase of stocks. As a wholly owned subsidiary, BMP operated as described in the letter. Sometime post acquisition, KCC developed a Global Business Plan to consolidate many of the wholly owned subsidiaries. The decision was made to move the operations taking place at BMP to Avent, Inc. (Avent). Although, BMP was a separate business entity and operated as such with regard to the licensed program, KCC had the ultimate ownership authority to move the operations as was discussed by telephone. The name did not change from BMP, but rather was dissolved as an entity in 2009.
    b. The contact for this information is Brenda Shelkey, office 678-352-6146 or mobile 678-654-8021 or email Brenda.Shelkey@kcc.com.
2. Describe any changes in personnel or duties that relate to the licensed program. Include training and experience for new personnel.

a. There were no changes to personnel or duties directly associated with the licensed program at the time of the acquisition other than directors and executive officers as noted in the letter dated December 13, 1999.

3. Describe any changes in the organization, location, facilities, equipment or procedures that relate to the licensed program.
    a. Please see the letters dated April 24, 2009 and June 9, 2009. These letters indicate the addition of the Avent facility as a distribution point and the amendment of name to Ballard Medical Products a wholly owned subsidiary of Kimberly-Clark Corporation.
    b. BMP has closed as an entity and all operations have transferred to the Avent facility. There were manufacturing equipment upgrades done concurrently with the relocation of the operations. These changes were approved by FDA for NDA 20-617. The procedures were modified only to provide for the new equipment. The ALARA program remains the same. The personnel responsible for the ALARA program and manufacturing the product did not change as all were relocated to the Avent facility.
4. Describe the status of the surveillance program (surveys, wipe tests, quality control) at the present time and the expected status at the time that control is to be transferred.
    a. For the acquisition of BMP and the relocation to Avent, the surveillance program is essentially equivalent to the one submitted in the Application dated August 18, 1999. Changes include facility diagram differences. The number and timing of surveys, the equipment used for detection and the differentiated levels for worker training remain the same. The ALARA program has been audited by the State of Utah Division of Radiation Control and the State of Arizona Radiation Regulatory Agency.
5. Confirm that all records concerning the safe and effective decommissioning of the facility will be transferred to the transferee or to NRC, as appropriate. These records include documentation of surveys of ambient radiation levels and fixed and/or removable contamination, including methods and sensitivity.
    a. All records concerning the decommissioning of the BMP facility remain with Kimberly-Clark.
    b. The State of Utah Division of Radiation Control performed the exit survey and released the facility for general use. The survey data indicated BMP met the most restrictive value (removable surface contamination level) listed in Table 1 of form DRC-14 for beta emitters, namely 1,000 disintegrations per minute beta per 100 square centimeters. This level is the most restrictive acceptable surface contamination level for uncontrolled release of facilities and equipment. The records include documentation of surveys of ambient radiation levels and fixed and/or removable contamination, including methods and sensitivity.
6. Confirm that the transferee will abide by all constraints, conditions, requirements, and commitments of the transferor or that the transferee will submit a complete description of the proposed licensed program.
    a. We confirm that Kimberly-Clark Corporation will abide by all constraints, conditions, requirements, and commitments of Ballard Medical Products.

(2) The letters included as "Conditions" in the license have been reviewed. There are no additional changes indicated to the license. Please note that our records indicate the Application (dated April 25, 2008 in your email) listed under "Conditions" bears the actual date of April 24, 2008. Included is a copy of the Application that we have on record. We are seeking confirmation that this copy is the one referenced in your email.

(3) We agree that the name and address on the license should be shown as:
Kimberly-Clark Corporation
1400 Holcomb Bridge Road
Roswell, GA 30076

We agree that the name and address of the distribution location listed on the license should be shown as:
Avent, Inc., A Subsidiary of Kimberly-Clark
6620 South Memorial Place, Suite 100
Tucson, AZ 85756

Please contact me if you require additional information.

Kind Regards,

Brenda Shelkey
Global Regulatory Affairs
(678) 352-6146
Brenda.Shelkey@kcc.com

Enclosure as indicated

24-April-2008

Duncan White
U.S. Nuclear Regulatory Commission
Mail Stop T8E24
11545 Rockville Pike
Rockville, MD 20852

Re: NRC License Number 43-23865-01E

Dear Mr. White

In accordance with 10 CFR § 30.38, Ballard Medical Products ("BMP"), a wholly owned subsidiary of Kimberly-Clark Corporation ("KCC"), requests that the Commission amend BMP's Nuclear Regulatory Commission ("NRC") Exempt Distribution License Number 43-23865-01E (the "license") to reflect certain changes for the KCC organization. Specifically, KCC plans to continue distribution of the PYtest kit, a carbon-14 urea capsule breath test, and the associated carbon-14 scintillation standards from its current BMP location as well as its Arizona licensed facility Avent. This application requests the addition of the Avent facility as a distribution site.

Avent is also a wholly owned subsidiary of KCC located in Tucson, AZ. The planned addition will not affect the activity as described in the license which authorizes distribution to persons exempt from NRC requirements; however, it will allow for both distribution sites to be operational. The manufacture of the PYtest kits and standard sets at BMP are allowed under UT 1800416 which is an FDA approved facility. Additionally, the manufacture of the PYtest kits and standard sets at Avent are allowed under AZ 16018 which is also an FDA approved facility.

Neither of the products, the PYtest kits or standard sets, will change as a results of this addition. The only change will be the addition of the Arizona distribution site. Additionally, the same management will have over-site for both facilities. The RSO for the Arizona facility has worked in the Utah facility for nearly 5 years in the production of these products, has trained with the current RSO and is licensed in Arizona. Up until the date of this request, BMP has reported to the management of Kimberly-Clark Health Care in Roswell, GA. After this amendment, BMP will continue to report to the management of Kimberly-Clark Health Care in Roswell, GA. The exact same reporting structure holds true for Avent before and after this amendment request. There will be no change in the control of the license.

The RSO for Avent is Dennis Morris. Should you have any questions or concerns please feel free to contact Brenda Shelkey, RSO of BMP.

We respectfully request your review of this amendment request.

Michael Kerwin
Director of Operations