

From: Chidakel, Susan
Sent: Monday, January 25, 2010 8:34 AM
To: Struckmeyer, Richard
Cc: Jones, Bradley
Subject: RE: Request to review possible Change of Control

Categories: Green Category

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I have reviewed this information and agree that based upon what you have provided, a change of control occurred. I am basing that determination upon the assumption that prior to 1999, when it was purchased by Kimberly Clark, Ballard, an independent company, made its own decisions about activities. I am actually confused as to why the staff did not believe that the actual transfer of control occurred at that point. Be that as it may, the following statements you have provided clearly show that Kimberly Clark now has full control of the formerly independent licensee:

"Kimberly Clark has closed the Ballard Medical Products facility and will no longer be distributing from that location."

"[License Amendment 03} guaranteed Kimberly Clark would be responsible for ensuring that Avent, Inc., would meet all NRC exempt distribution license requirements."

Please let me know if you believe there is any contradictory information that would negate my assumption or conclusion in this regard.

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From: Struckmeyer, Richard
Sent: Friday, January 22, 2010 3:25 PM
To: Chidakel, Susan
Subject: RE: Request to review possible Change of Control

Susan,

In retrospect I see why the request is not clear, even though it seemed obvious to me when I wrote it. I couldn't see the forest for the trees.

The license renewal application came from Ballard, but it appears to me that Kimberly Clark actually has control over the license. Neither company ever applied for to amend the license to incorporate this apparent change of control. The issue only rose to the surface when Ballard sent in its request for license renewal.

My request is for OGC's (your) opinion as to whether a change of control did in fact take place, based on the information I provided in my earlier email.

I hope I have phrased this correctly.

Let me know if I can provide additional information.

Thank you,

Richard Struckmeyer
Licensing Branch
FSME

From: Chidakel, Susan
Sent: Friday, January 22, 2010 3:09 PM
To: Struckmeyer, Richard
Subject: RE: Request to review possible Change of Control
Importance: High

Hi. I started briefly to look at this and I'm not sure what you are asking us to do. You say what you believe but did you want us to confirm that? What exactly is the issue?
thanks
susan

From: Struckmeyer, Richard
Sent: Friday, January 15, 2010 2:43 PM
To: Chidakel, Susan
Subject: Request to review possible Change of Control

Susan,

An exempt distribution licensee, Ballard Medical Products (docket number 030-34969; exempt-distribution license number 43-23865-01E), has applied for an amendment to renew its license, to change the location from which its product will be distributed, and to modify the licensee name to "Avent, Inc., a subsidiary of Kimberly-Clark." We (the Licensing Branch, FSME) believe this will require the renewal of the existing license, followed immediately by termination of this license and issuance of a new license to reflect the new location. The new location may be in Arizona or possibly in Georgia, depending on the outcome of the review of a possible change of control over the license.

For reference, the companies involved are Kimberly-Clark, located in Georgia; Ballard Medical Products, in Utah; and Avent, Inc., in Arizona.

(This is a rather long email; I hope I am not overdoing it.)

Background

As part of the review of this amendment request, I also reviewed the licensee's previous license amendments in order to understand the changes that have occurred with regard to its corporate structure. Based on this review, it is not clear which corporate entity has control over this license.

Three amendments have been processed following the issuance of the original NRC Exempt Distribution License in 1999 (this can be found beginning on page 22 of ML003670331).

(1) The licensee's letter dated December 14, 1999 (beginning on page 7 of ML003670331), notified the NRC of a planned management change, related to the acquisition of Ballard Medical

Products and its wholly owned subsidiary Tri-Med Specialties, Inc., by Kimberly-Clark Corporation. The licensee indicated that Kimberly-Clark had not implemented any change in the Ballard or Tri-Med corporations that would constitute a change of control or authority over either license. Amendment 01 to the license was issued on December 21, 1999, to incorporate this change.

(2) The licensee's letter dated June 4, 2000 (beginning on page 5 of ML003759684), requested an amendment to Ballard's license to reflect certain changes planned for the Ballard organization. involving the consolidation of its operations including moving its wholly owned subsidiary, Tri-Med Specialties, Inc., from Charlottesville, Virginia to Ballard's main facility in Draper, Utah. A subsequent letter, dated August 8, 2000 (ML003745425), provided a copy of the Food and Drug Administration (FDA) letter that approved the change of the manufacturing location from Charlottesville, Virginia to Draper, Utah. Amendment 02 to the license was issued on October 11, 2000, to incorporate this change. The Tri-Med Specialties licenses were subsequently terminated.

(3) The licensee's letter dated April 24, 2008 (ML081290700), requested the addition of a distribution location at Avent, Inc., a subsidiary of Kimberly-Clark, in Tucson, Arizona. Also, the licensee's letter dated June 09, 2008 (ML081840523), requested that the name of its company, as listed on the license, be changed to "Ballard Medical Products, A Subsidiary of Kimberly-Clark." Amendment 03 to the license was issued on June 18, 2008, to incorporate these changes.

To summarize these previous licensing actions, it appears that Ballard obtained the original license as an independent corporate entity, then the license was amended to include Tri-Med as an subsidiary of Ballard, and to acknowledge the purchase of Ballard by Kimberly-Clark (a separate corporate entity) while Ballard remained as an independent corporate entity (amendment 01). A subsequent amendment reflected the consolidation with its wholly owned subsidiary, Tri-Med Specialties, Inc., from Charlottesville, Virginia to Ballard's main facility in Draper, Utah (amendment 02). Next, the licensee requested the addition of Avent, Inc, another subsidiary of Kimberly-Clark (and an apparently independent corporate entity separate from both Ballard and Kimberly-Clark) as a distribution location under the Ballard license (amendment 03).

Current Application for Amendment (dated September 16, 2009),

In addition to renewal, the licensee also requested that the license also be amended to:

- change the name of the company to Avent, Inc., a Subsidiary of Kimberly-Clark;
- delete from its license the Ballard Medical Products location as a distribution site; and
- move its place of business to the Avent, Inc., facility in Tucson, Arizona.

Furthermore, the following statements were made in this application:

"In support, Kimberly-Clark has closed the Ballard Medical Products facility and will no longer be distributing from that location. License amendment number 03 added the Avent, Inc. facility as a distribution site. That amendment also guaranteed Kimberly-Clark would be responsible for ensuring that Avent, Inc. would meet all NRC exempt distribution license requirements. The

management and direct reporting relationships for the Avent, Inc. facility are the same as for the Ballard Medical Products facility.”

“To demonstrate that point, find enclosed the facility structure chart for Kimberly-Clark. It shows the ATW (Avent Tucson West) facility as reporting up to the Kimberly-Clark Health Care site in Roswell, Georgia. Additionally, two organizational charts are included. One is for the structure of Kimberly-Clark and the other is for the Avent Tucson facility. The Vice President and Director positions are the same on both charts. This structure is identical to the structure as explained in amendment 03. The same level of management commitment and oversight by Kimberly-Clark exists for the Avent, Inc. facility.”

Review of Licensee's Amendment Request

In reviewing the amendment requests, I considered relevant information such as the statements quoted above, and the apparent uncertainty as to whether Avent is a subsidiary of Ballard or of Kimberly-Clark, as explained in the following paragraphs:

(a) While considering the documentation related to Amendment 03, I noted a possible ambiguity with respect to whether Avent, Inc. could serve as a distribution location for Ballard Medical Products. In order to do so, if Avent was not a subsidiary of the corporate entity having control over the license, it would be required to apply for and receive an exempt-distribution license, so as to comply with 10 CFR 30.21(c).

(b) According to 10 CFR 30.21(c): “Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules shall apply for and receive a specific license pursuant to § 32.21 of this chapter.” Therefore, if Avent, Inc., was an independent company or a wholly-owned subsidiary of Kimberly-Clark Corporation at the time of this amendment request, and not under the control of Ballard Medical Products, it (or its parent company) would have been required to have an NRC exempt-distribution license.

I sent the licensee a letter “Acknowledgment Of Timely Receipt Of Renewal Application And Request For Additional Information,” dated October 29, 2009 (ML093030547). I have already summarized the issues pertaining to the possible change of control that are covered in this letter, but you may wish to review it. I received a response dated January 5, 2010 (ML100150703).

Summary of Licensee's Response (dated January 5, 2010)

Avent, Inc (Avent) was not a wholly owned subsidiary of Ballard Medical Products (Ballard). Both Avent and Ballard are wholly owned subsidiaries of Kimberly-Clark corporation (Kimberly-Clark). Both are considered closed corporations. The same reporting structure exists for both facilities as I attempted to demonstrate with the corporate organizational structure maps. Additionally, neither Ballard nor Avent, being wholly owned subsidiaries of Kimberly-Clark, is able to exercise fiduciary responsibilities independent of Kimberly-Clark. Further, all financial resources for operations and licensures are controlled by and provided by Kimberly-Clark.

There were no transfers of stock, assets or mergers with the movement of equipment from: the Ballard location to the Avent location. As wholly owned subsidiaries, all assets of both facilities

are owned by Kimberly-Clark. There were no changes in personnel. The plant manager and several employees, including those that oversee the production of the PYtest product were all transferred to the Avent facility with the closure of the Ballard facility. Please see the Annual summary Material Transfer Report, which is attached.

The control of the radiation safety program and licensed material takes place at the plant level, Avent, with oversight and approval at the corporate level, Kimberly-Clark. The authority to provide the necessary resources to achieve regulatory compliance is requested at the plant level, Avent and provided at the corporate level. This process was the same as exercised at Ballard and Kimberly-Clark.

Please let me know if I can provide additional information, or clarify this request.

Thank you,

Richard Struckmeyer
Licensing Branch
FSME

E-mail Properties

Mail Envelope Properties (320204600EA7B9408FE833FF15E4FF7D0A32C2D7CA)

Subject: RE: Request to review possible Change of Control
Sent Date: 1/25/2010 8:34:01 AM
Received Date: 1/25/2010 8:34:01 AM
From: Chidakel, Susan

Created By: Susan.Chidakel@nrc.gov

Recipients:
Richard.Struckmeyer@nrc.gov (Struckmeyer, Richard)
Tracking Status: None
Bradley.Jones@nrc.gov (Jones, Bradley)
Tracking Status: None

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Options

Expiration Date:

Priority: olImportanceNormal

ReplyRequested: True

Return Notification: False

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Recipients received: