

July 31, 2018

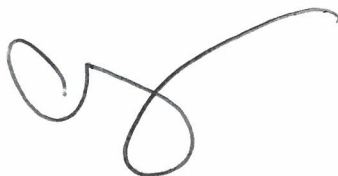
Materials Safety Licensing Branch
Division of Material Safety, State, Tribal, and Rulemaking Programs
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
One White Flint North 11555 Rockville Pike
Rockville, MD 20852-2738

Re: Change of Ownership for Avent, Inc.

To Whom it Concerns,

Avanos, Inc. is submitting this letter as notification of ownership change for the Avent Inc. license for manufacture of PYtest* Urea Breath Test from Halyard Health Inc., to Avanos Medical, Inc. effective June 30, 2017. Halyard Health, Inc. has rebranded its medical device business and changed its name to Avanos Medical, Inc. to emphasize the company's focus on innovating with speed to deliver better, more sustainable patient outcomes.

The Avent facility in Tucson, AZ will also be changing its name and ownership from Halyard Health, Inc. to Avanos Medical, Inc. The effective date for that change is also June 30, 2017. Please direct any questions on this ownership change to my attention.



Monica King, MBA
Associate Director, Regulatory Affairs
Avanos Medical, Inc.
5405 Windward Parkway
Alpharetta GA 30004
Monica.king@hyh.com
[678-477-4165](tel:678-477-4165)

REC RG1 0803 18 AM 10:18

NRC FORM 313

(10-2017)
10 CFR 30, 32,
33, 34, 35, 36,
37, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR
MATERIALS LICENSE

APPROVED BY OMB: NO. 3150-0120

EXPIRES: 06/30/2019

Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Information Services Branch (T-2 F43), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollect.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

INSTRUCTIONS: SEE THE CURRENT VOLUMES OF THE NUREG-1556 TECHNICAL REPORT SERIES ("CONSOLIDATED GUIDANCE ABOUT MATERIALS LICENSES") FOR DETAILED INSTRUCTIONS FOR COMPLETING THIS FORM: <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/>. SEND TWO COPIES OF THE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

MATERIALS SAFETY LICENSING BRANCH
DIVISION OF MATERIAL SAFETY, STATE, TRIBAL AND RULEMAKING PROGRAMS
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA,
GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE,
NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO,
RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN
ISLANDS, OR WEST VIRGINIA,

SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND
APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

IF YOU ARE LOCATED IN:

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS,
LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH
DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS,
UTAH, WASHINGTON, OR WYOMING,

SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
1600 E. LAMAR BOULEVARD
ARLINGTON, TX 76011-4511

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

- ☐ A. NEW LICENSE
- ☒ B. AMENDMENT TO LICENSE NUMBER 10-239890-15
- ☐ C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT (Include zip code)

Avanos Medical, Inc.
5405 Windward Parkway
Alpharetta GA 30004

3. ADDRESS WHERE LICENSED MATERIALS WILL BE USED OR POSSESSED

Avent
6620 S. Memorial Place
Suite 100
Tucson, AZ 85756

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Dennis Morris

BUSINESS TELEPHONE NUMBER
520-241-5564

BUSINESS CELLULAR TELEPHONE NUMBER
520-241-5564

BUSINESS E-MAIL ADDRESS
dennis.morris@hyh.com

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL

- a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE FEES (Fees required only for new applications, with few exceptions*)
(See 10 CFR 170 and Section 170.31)

*Amendments/Renewals that increase the scope of the existing license to a new or higher fee category will require a fee.

FEE
CATEGORY

NA

AMOUNT
ENCLOSED \$

0.00

PER THE DEBT COLLECTION IMPROVEMENT ACT OF 1996 (PUBLIC LAW 104-134), YOU ARE REQUIRED TO PROVIDE YOUR TAXPAYER IDENTIFICATION NUMBER. PROVIDE THIS INFORMATION BY COMPLETING NRC FORM 531: <https://www.nrc.gov/reading-rm/doc-collections/forms/nrc531info.html>.

13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 37, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE

Monica King, Associate Director, Regulatory Affairs

SIGNATURE

DATE

7/31/18

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		
APPROVED BY				DATE	

NRC License Amendment

Avanos Medical

7/31/18

Additional Information for NRC License Amendment Form 313

Halyard Health, Inc. has rebranded its medical device business and changed its name to Avanos Medical, Inc. to emphasize the company's focus on innovating with speed to deliver better, more sustainable patient outcomes.

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5a Carbon-14 Urea in Capsules and Liquid Scintillation Standards

5b Carbon-14 Urea in Capsules and Liquid Scintillation Standards

5c 10 millicuries (mci) Refer to current license, condition 10

6. Material will be used to manufacture the 14C Urea, drug substance and PYtest radiopharmaceutical capsules

7 There is no change from the current license This license amendment is related to name change only Dennis Morris, Quality Manager, has the required training and expertise He has been in his position since 2008

8 There is no change from the current license This license amendment is related to name change only

9. There is no change from the current license This license amendment is related to name change only

10 There is no change from the current license This license amendment is related to name change only

11 There is no change from the current license This license amendment is related to name change only