



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
WASHINGTON, D.C. 20555-0001

February 1, 2019

KH Imports, LLC
ATTN: Daniel Hall
P.O. Box 3098
Zephyrhills, FL 33539

SUBJECT: KH IMPORTS, LLC, REQUEST FOR ADDITIONAL INFORMATION

Dear Mr. Hall:

This letter is in response to your application, U.S. Nuclear Regulatory Commission (NRC) Form 313, dated November 1, 2018, requesting an exempt distribution license and a sealed source and device evaluation.

We do not have sufficient information to complete the review of your application. In the enclosure to this letter you will find the list of the questions and items not addressed in your application.

Please be aware that upon your request, proprietary information submitted to the NRC may be withheld from public disclosure. To do this, you must follow the procedures in Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390(b) including requesting withholding at the time the information is submitted and complying with the document marking and affidavit requirements set forth in 10 CFR 2.390(b)(1).

We will continue our review upon receipt of this information. If we do not receive your reply within 30 calendar days from the date of this letter, we will consider your application as having been abandoned by you. This action would be without prejudice to the resubmission of another application with the required information.

Your application for a distribution license should not contain information concerning the possession and use of radioactive material because that is covered in a separate possession license.

Any correspondence regarding your amendment application should reference Control Number 610716.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

D. Hall

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If you have any questions, please contact Celimar Valentin-Rodriguez at (301) 415-7124, or by e-mail at Celimar.Valentin-Rodriguez@nrc.gov regarding the sealed source and device registration, and Richard Struckmeyer at (301) 415-5477, or by e-mail at Richard.Struckmeyer@nrc.gov regarding the exempt distribution license.

Sincerely,

/RA/

Richard K. Struckmeyer
Materials Safety Licensing Branch
Division of Material Safety, States, Tribal
and Rulemaking Program
Office of Nuclear Material Safety
and Safeguards

Docket No. 030-39144

Enclosure:
Request for Additional Information

D. Hall

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KH IMPORTS, LLC, REQUEST FOR ADDITIONAL INFORMATION DATED FEBRUARY 1, 2019

Certified Mail No. 7015 3010 0000 7901 5737

ML18340A070 (pkg)

ML19031C811 (Letter)

OFC	NMSS/MSLB	NMSS/MSLB	NMSS/MSLB	NMSS/MSLB	NMSS/MSLB
NAME	RStruckmeyer	DWeaver	CValentin-Rodriguez	THerrera	RStruckmeyer
DATE	01/31/2019	01/31/2019	02/1/2019	02/1/2019	02/1/2019

OFFICIAL RECORD COPY

KH Imports, LLC
Application dated November 1, 2018
Request for Additional Information

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the KH Imports, LLC, application dated November 1, 2018, and determined that additional information is needed. In order to continue with our review, please address the issues listed below.

The information related to review of your sealed source and device amendment application is required by Title 10 of the *Code of Federal Regulations* (10 CFR) 32.210 and is described in the relevant guidance document NUREG-1556, Volume 3, Revision 2, titled "Applications for Sealed Source and Device Evaluation and Registration."

The information related to review of your exempt distribution license application is required by 10 CFR 32.14, 32.15, 32.16, 32.22, 32.23, and 32.24, and is described in the relevant guidance document NUREG-1556, Volume 8, "Program-Specific Guidance About Exempt Distribution Licenses."

A. Questions Related to the Sealed Source and Device Application

1. In your application, you requested a maximum activity of 250 mCi of H-3 per watch. In addition you indicated that some watches may contain up to 100 individual gaseous tritium light sources. In the information that you provided for each of the watch models that KH Imports, LLC intends to distribute, the maximum source activity that was identified was 205 mCi for the watch model number NM2092C. This same watch model also contains 75 individual sources. Please note that since you have not provided information to support a maximum activity of 250 mCi per watch or a watch that contains 100 individual sources, the maximum activity that will be approved for distribution will be 205 mCi, with that watch containing 75 individual sources.
2. In your application, you only provided engineering drawings for four different models: CM2068D, CM2052D, DM1022A, and DM2076C. Two of these models, CM2068D and CM2052D, contain less than 25 mCi of H-3, and thus do not require a sealed source and device registration certificate, as specified in 10 CFR 30.15. Please discuss how the engineering drawings and pictures for the other two models represent the other 62 models in your application that require a sealed source and device registration certificate. If these drawings and pictures are not representative of all the other models that do require a sealed source and device registration certificate, please submit additional engineering drawings for the other models.
3. Please discuss your rationale for only testing eight models out of the 97 models that you have listed in your application. We also note that the model numbers submitted in the prototype testing reports do not all align with the models that KH Imports, LLC intends to distribute. Please explain the reason for the differences.

Enclosure

4. Please submit KH Imports' Quality Assurance Program. The documentation submitted in Attachment G pertained to Ball Watch Company's quality control procedures. Please be aware that, per NUREG-1556, Vol. 3, Rev. 2, Section 10.7, as a U.S. distributor, you must periodically audit the foreign facility where your products are manufactured. Also, copies of all records must be maintained in the U.S., as specified in 10 CFR 110.53(b).

B. Questions Related to the Exempt Distribution License Application

1. 10 CFR 32.14(a) and 32.22(a)(1) require the applicant to satisfy the general requirements specified in Section 30.33 of 10 CFR. To do so, please provide a copy of your possession and use license from the State of Florida. Please note that an exempt distribution license will not be issued until we receive a copy of your possession and use license.
2. 10 CFR 32.22(a)(2)(iv) requires the applicant to submit the solubility in water and body fluids of the forms of the byproduct material identified in paragraphs (a)(2) (iii) and (xii) of this section. You provided information on page 3 and in Attachment 6 of your exempt distribution license application about the maximum oxide content; however, this did not explicitly state the degree of solubility. Please provide this information in your response to this request for additional information.
3. Based on the information you provided in your model list (Attachment 1 to your application), watch numbers 6, 82, 84, and 88 have a total activity less than 25 mCi, but have dials with more than 15 mCi. Please be aware that these models are subject to the regulations in 10 CFR 32.22 and will be included on the sealed source and device registration certificate because they exceed the 15 mCi of tritium per dial allowed by 10 CFR 30.15(a)(iii). Please inform us if any of this information is incorrect so that appropriate modifications to your exempt distribution license and registration certificate can be made.

6) Name: Fireman Storm Chaser Pro
Model Number: CM3090C
82) Name: Fireman Racer 43mm
Model Number: NM2288C-J
84) Name: BALL for BMW Classic
Model Number: NM3010D-CJ
88) Name: Fireman Racer DLCModel
Number: NM3098C-1J

4. Watch numbers 35, 94 and 95 in your model list have no mention of an hour hand. Please confirm the accuracy of this information, or provide additional information.

35)Name: Fireman Victory
Model Number: NM2098C
94) Name: BALL for BMW Power Reserve
Model Number: PM3010C-J
95) Name: BALL for BMW Power Reserve DLC
Model Number: PM3010C-1CJ

5. Watch numbers 1, 2, 3, 5, 7, 33, 36, 42, 43, 48, 49, 53, 56, 57, 58, 60, 62, 63, 70, 72, 83, 89, 90, 91, 92, 94, and 95 in your model list have quantities of tritium per hand, per dial, and per timepiece (total) below the respective quantities stated in 10 CFR 30.15(a)(1); therefore these models are subject to the regulations in 10 CFR 32.14, and will not be included on the sealed source and device registration certificate. Please inform us if any of this information is incorrect so that appropriate modifications to your exempt distribution license and registration certificate can be made.