



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

January 23, 2018

Top Shelf LED, Inc.,  
dba Grower's Choice  
ATTN: Leonardo Day, CEO  
1500 S. Milliken Ave., Unit B  
Ontario, CA 91761

SUBJECT: SECOND REQUEST FOR ADDITIONAL INFORMATION

Dear Mr. Day:

This letter is in response to your application, U.S. Nuclear Regulatory Commission (NRC) Form 313, dated August 31, 2017, requesting an exempt distribution license, and to your reply, dated December 22, 2017, to our request for additional information (RAI).

We do not yet 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 fully addressed in your application or response to our RAI.

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 601516.

L. Day

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If you have any questions, please contact me at (301) 415-5477, or by e-mail at [Richard.Struckmeyer@nrc.gov](mailto:Richard.Struckmeyer@nrc.gov).

Sincerely,

**/RA/**

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

Docket No. 030-39076

Enclosure:  
Second Request for Additional Information

L. Day

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TOP SHELF LED, INC., SECOND REQUEST FOR ADDITIONAL INFORMATION

Date: January 23, 2018

**ML17306A018 (pkg.)**

**ML18023A142 (Letter)**

OFC	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB
NAME	Richard Struckmeyer	Deborah Weaver	Richard Struckmeyer
DATE	01/23/2018	01/23/2018	01/23/2018

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## TOP SHELF LED, INC., APPLICATION DATED AUGUST 31, 2017 SECOND REQUEST FOR ADDITIONAL INFORMATION

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the Top Shelf LED, Inc., application dated August 31, 2017, as well as your December 22, 2017, reply to our request for additional information (RAI), and has 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 exempt distribution license application is required by Title 10 of the *Code of Federal Regulations*, Chapter 32 (10 CFR 32), Sections 32.14 and 32.15, and is described in the relevant guidance document NUREG-1556, Volume 8, titled "Program-Specific Guidance about Exempt Distribution Licenses," available on the NRC public web site (<https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v8/>).

In our initial RAI we stated nine regulatory requirements for which your application lacked sufficient information. The responses to several of these items were not sufficient to allow us to approve your request for an exempt distribution license. Each of the first eight items is repeated below and, where applicable, annotated with a description of the additional information needed. The ninth item did not require a specific response.

Please provide the information required by each of the following regulations. You may need to obtain some of this information from your supplier(s). Note that it is the applicant's responsibility to confirm the validity of all information.

1. 10 CFR 32.14(a) requires 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 California. 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 32.14(b)(1) requires the applicant to submit the chemical and physical form and maximum quantity of byproduct material in each product. *No further information is required.*
3. 10 CFR 32.14(b)(2) requires the applicant to submit details of construction and design of each product. Applicants should provide a list of all models of each type of product they wish to distribute. Applicants should provide detailed engineering drawings of each basic device containing the overall dimensions, the minimum and maximum dimensions for each device, the tolerances, description or identification of the construction materials, and the source mounting configuration(s) to be used with each device. Your application appears to indicate two types of arc tubes, quartz and ceramic polycrystalline alumina. The requested information must be provided for each type of material used (such as steel, aluminum, or plastic) in each type of tube. If you plan to distribute various models of devices within groups or series (where there are similarities in the design and construction of the devices within each series), you should specify the above information for each series type.

Enclosure

- Although you provided engineering drawings for the products you plan to distribute, these drawings contained numeric dimensions without any indication of the units (e.g., inches or centimeters) of these dimensions. Please provide the appropriate units.
  - Several of the drawings contain written text that is not translated into English. Please provide English translations for any text that is pertinent to the information requested in item 3, and specify whether each drawing identifies a particular lamp model, or a series containing lamps that are similar but have varying model numbers.
4. 10 CFR 32.14(b)(3) requires the applicant to submit the method of containment or binding of the byproduct material in the product. *No further information is required.*
  5. 10 CFR 32.14(b)(6) requires the applicant to submit the proposed method of labeling or marking each unit and its container with the identification of the manufacturer or initial transferor of the product and the byproduct material in the product. Note: 10 CFR 32.15(d)(1) requires labeling or marking of each unit and its container so that the manufacturer or initial transferor of the product and the byproduct material in the product can be identified. Please provide examples of your labels in the form of drawings, copies, or photographs.
    - The information you provided in response to this item did not appear to identify the byproduct material in the lamps, neither on the lamps themselves nor on the container(s). Please note that NUREG-1556, Volume 8, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Exempt Distribution Licenses," states: "For those products requiring labeling, the regulations state that the item distributed must display the required label, or if this is not possible, then the label should be placed on the product's immediate container. For example, if an electron tube is too small to label, then the label should be placed on the next smallest container or its immediate container, such as the bubble pack containing the electron tube."
  6. 10 CFR 32.14(b)(7) requires the applicant to submit the radiation level and the method of measurement for products for which limits on levels of radiation are specified in Section 30.15 of this chapter. *No further information is required.*
  7. 10 CFR 32.14(d) requires the applicant to provide information to show that the byproduct material is properly contained in the product under the most severe conditions that are likely to be encountered in normal use and handling. *No further information is required.*
  8. 10 CFR 32.15(b)(1) states that no person licensed under Section 32.14 shall transfer to other persons for use under Section 30.15 of this chapter or equivalent regulations of an Agreement State any part or product tested and found defective under the criteria and procedures specified in the license issued under Section 32.14, unless the defective part or product has been repaired or reworked, retested, and found by an independent inspector to meet the applicable acceptance criteria.

- In your response to this item you wrote: "All product containers are labeled ... All defective or broken product will be isolated ... and disposed of properly. It would be transfer to any other facility or users."

The last sentence in the above paragraph does not appear to convey the meaning you intended. Please provide a corrected statement.