

From: [Scott Wilson](#)
To: marco_torres_delgado@baxter.com
Cc: jose.carerro@baxter.com
Subject: Request for Additional Information; Baxter Healthcare of Puerto Rico; License Number 52-21175-01; Docket Number 03019882; Mail Control Number: 638627
Date: Wednesday, May 29, 2024 1:29:00 PM
Importance: High

Marco M Torres
Sterilization Principal Engineer – Radiation Safety Officer
Baxter Healthcare of PR
Medical Products Division
PO Box 1389 / Aibonito, Puerto Rico 00705

RE: Baxter Healthcare of Puerto Rico; License Number 52-21175-01; Docket Number 03019882; Mail Control Number: 638627

Mr. Torres,

This is a follow up message to our phone call today. To continue our review of your request letter dated December 13, 2023, we need the following information:

1. Copies of the organizational chart showing the organization before and after the change in business designation and including the parent company before and after.
2. A signed memo stating the parent company did not change and the only change was in the corporation from an SA to an LLC corporation.

The following requests are independent of the request you sent.

1. Please provide an update regarding the overdue license fees. Have they been paid? We cannot revise the license with the new company name until fees are paid in full.
2. Due to the name change to an LLC, the license financial assurance documents need to be updated. You stated today that the updates are being completed. Can you estimate when we can expect to receive the updated financial assurance documents?

Any documents you provide will be made available to the public unless you provide justification for withholding it in accordance with 10 CFR 2.390

<<https://www.ecfr.gov/current/title-10/section-2.390>>

The documents can be provided via email attachment, through US Mail, or by facsimile. My email address and the office address are below.

Thank you for your cooperation.

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