U.S. FOOD & DRUG ADMINISTRATION

2/19/2021

[redacted]

Dear [redacted]

Due to the current situation in your area (i.e SARS-CoV-2 (COVID-19)), the United States Food and Drug Administration (FDA) is conducting inspections on a limited basis at this time. On Thursday February 25, 2021, I would like to conduct a Remote Regulatory Assessment (RRA) of [redacted] located at [redacted].

An RRA is a review of records and information provided by your firm to gain information and to evaluate your Quality System. The RRA is a *voluntary activity* that will not result in regulatory action due to non-participation.

The RRA may be limited in scope or terminated at the discretion of the Agency. The RRA is limited to reviewing information that can be provided electronically, and your firm's ability to do so should factor in your decision for participation. Refusal to provide information during the RRA is not a refusal under FDA's inspection authority found in Section 704 of the Federal Food Drug and Cosmetic Act (21 USC 374).

At the conclusion of the RRA, a discussion of findings will be held with management officials describing any items I want to bring to your attention. Based on the outcome of findings from the RRA, FDA may consider further communication and/or action. If significant deficiencies are noted, FDA may begin an onsite regulatory inspection for the purpose of protecting public health. If this is necessary, your designated management official will be notified.

Whether you decide to participate or not in the RRA, please respond to me at leo.lavi@FDA.HHS.GOV or [redacted] within five business days with your decision. When you respond, please provide the name, e-mail and telephone number of the primary contact during the RRA. If there are any questions or concerns that I can't address, please feel free to contact [redacted] Director of Investigations Branch Tel: [redacted] email is [redacted]@fda.hhs.gov.

Thank you for considering this request.

[redacted]

Sincerely,

[redacted]

U.S. Food and Drug Administration
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Irvine, CA 92612
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