

“Summary of Teleconference To Notify BN Regarding Monkeypox Indication.”

Date: March 5, 2019, 2:15 PM EST

Subject: Initiated by CBER to notify BN regarding Monkeypox indication as well as providing answer to BN’s question on submission of responses to 483.

CBER Attendees:

Bharat Khurana, DVM, PhD, MBA.
Sudhakar Agnihothram, PhD

BN Attendees:

Renee Boerner, PhD

Summary:

BN was notified of the following points

- CBER is proceeding with considering a monkeypox indication for this product and will provide draft wording for the package insert as the review progresses.
- BN may electronically submit their responses to 483 as an amendment (inspection related) to BLA and addresses the amendment to DMPQ Address listed on the 1st page of 483.