[redacted]

Objet: RE: [WARNING: MESSAGE ENCRYPTED]FDA FMD145 EIR

Expéditeur: <Graham.Leslie@fda.hhs.gov>
Date: 17 septembre 2019 à 14:32:44 UTC+2
Destinataire: <christian.poinsot@laboratoireicare.com>
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09/17/2019
Dr. Christian Poinsot
Laboratoire Icare
Biopole Clermont-Limagne 63360 Saint-Beauzire, Puy de Dome FRANCE

Dear Dr. Poinsot:

The U.S. Food and Drug Administration (FDA) conducted an inspection at Laboratoire Icare, FEI 3008220949, located at Biopole, Clermont Limagne, St Beauzire, Puy de Dome FRANCE, from 08/01/2019 to 08/02/2019. FDA has determined that the inspection classification of this facility is "no action indicated" ("NAI"). Based on this inspection, this facility is considered to be in an acceptable state of compliance with regards to current good manufacturing practice (CGMP).

This letter is not intended as an endorsement or certification of the facility. It remains your responsibility to ensure continued compliance with CGMP.

An inspection classification of NAI for CGMP compliance will not directly negatively impact FDA's assessment of any pending marketing application referencing this facility. Please note, however, that application approval will depend on a product- and application-specific facility assessment conducted by the appropriate CDER or CVM review office. This letter does not address or reflect FDA's decision making with respect to any potential non-CGMP compliance issues.

FDA has concluded that this inspection is ''closed'' under 21 CFR 20.64(d)(3), and we are enclosing a copy of the narrative portion of the Establishment Inspection Report (EIR). It may reflect redactions made by FDA in accordance with the Freedom of Information Act (FOIA) and 21 CFR part 20. This, however, does not preclude you from requesting additional information under FOIA.

If you have any questions regarding this letter, you may contact Steven Eastham via telephone at 513-246-4134 x1103 or email at Steven.Eastham@FDA.HHS.GOV

Sincerely,

Graham Leslie
PROGRAM SUPPORT SPECIALIST
300 River Place, Suite 5900 Detroit, MI 48207-4291