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DIÁRIO OFICIAL DA UNIÃO

Translation of National Health Surveillance Agency - Official Gazette

RESOLUTION - RE NO. 2.299, JUNE 14, 2024

THE GENERAL MANAGER OF HEALTH INSPECTION AND SUPERVISION OF THE NATIONAL HEALTH SURVEILLANCE AGENCY, in the use of the powers conferred on him by art. 140, combined with art. 203, I, § 1 of the Internal Regulations approved by the Resolution of the Collegiate Board - RDC nº 585, of December 10, 2021,

Considering the non-compliance with the requirements of Good Manufacturing Practices for Pharmaceutical Ingredients, or the non-compliance with the procedures for petitions submitted for analysis, recommended in current legislation, resolves:

Art. 1 Reject the Request(s) for Certification of Good Manufacturing Practices for Pharmaceutical Ingredients from the company(ies) listed in the ANNEX.

Art. 2 This Resolution comes into force on the date of its publication.

Manufacturer: Provepharm Life Solutions - B001214

Address: 22 Rue Marc Donadille, Marseille, Provence-Alpes-Cote D'azur 13013

Country: France

Manufacturer Number: B.001214

File Number: 0155260/24-3

SUBJECT: 70158 - PHARMACEUTICAL INGREDIENT - Certification of Good Manufacturing Practices for International Industry, except Mercosur - chemical synthesis

REASON FOR REJECTION: In compliance with article 3, item IV, and article 4, §§ 1 and 2 of RDC nº 672/2022: failure to present mandatory documentation for granting the requested certification, due to the absence of the last complete report generated product quality review (PQR) or, when the PQR is not available, the validation of the manufacturing process for the petitioned active pharmaceutical ingredient, as such documents were not forwarded by third party addition, as informed by the petitioner in its own document. It should be noted that the deadline for such an addition (30 days) has expired, as the petition was filed on 02/08/2024.