

2 February 2026

To whom it may concern,

The FDA conducted an audit of Innovation Specialties, FEI 1000300091, against 21 CFR 210 and 211 drug establishment GMPs in December 2023. The recommendation of the FDA agent was for Innovation Specialties to de-register their facility as a drug establishment. The agency views the OTC drug business processes conducted at Innovation Specialties' facility to be Private Label Distribution of drug products. Although logos are applied to the product labels, all FDA required information is already printed on the labels when Innovation receives drug products from their manufacturer. Therefore, the manufacturer is completely responsible for all drug manufacturing GMPs and Innovation is responsible for Private Label Distributor GMPs. Part of the PLD responsibility is supplier verification to ensure their partners are complying with drug GMPs when producing the OTC drug products Innovation distributes in the United States.

Innovation Specialties does not have a drug establishment registration and therefore will not be found during a search of the FDA drug establishment database. Innovation Specialties maintains their NDC listing files and assures accurate updates of any label changes, as well as annual listing certifications when required. Their drug product listings can be found by searching the FDA's National Drug Code database or DailyMed.

Should you have questions or concerns with this information, please contact Ryan Lauzon at [ryan@innovation-line.com](mailto:ryan@innovation-line.com) for further details.

Thank you,



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