

August 21, 2018

Kyowa Hakko Bio Co., Ltd.

**Receipt of FDA Warning Letter at Hofu Plant of Kyowa Hakko Bio Co., Ltd.**

Kyowa Hakko Bio's Hofu Plant (Yamaguchi Prefecture, Japan) was inspected by the US Food & Drug Administrations (FDA) in September 2017 and was issued a Warning Letter (WL) on August 10, 2018. The FDA's observations include concerns about Data Integrity.

We confirm that there are no quality deficiencies in our products. At this time, we are not instructed to recall our products and/or suspend shipments due to this WL.

If you have any questions, please contact us.

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