



January 16, 2025

KYOWA HAKKO BIO CO.,LTD.

**Notification: KYOWA HAKKO BIO Co., Ltd. received Close-Out Letter
related to Warning Letter from the FDA**

We, KYOWA HAKKO BIO Co., Ltd., (Head office: Nakano-ku, Tokyo, Japan, President & CEO Mr. Koji Fukada), inform that the Food and Drug Administration (FDA) conducted an inspection at Yamaguchi Production Center (Hofu plant) in September 2024 and we received Close-Out Letter which indicates the inspection classification is “NAI: No Action Indicated” as of January 2, 2025 from FDA.

Based on the evaluation, Hofu plant is considered to be in an acceptable state of compliance with regard to current good manufacturing practice (cGMP) and completed corrective actions in response to Warning Letter dated August 10, 2018.

We have continuously maintained compliance and will provide high quality products and services for valued customers throughout every process by quality activities of integrity.