

As you may be aware, Fresenius Kabi Oncology Limited (“FKOL”) recently entered into a criminal settlement with the United States in connection with FKOL’s intentional concealment of records from the United States Food and Drug Administration (“FDA”) during a 2013 FDA inspection of an FKOL manufacturing plant located in Kalyani, West Bengal, India (the “Kalyani plant”). This letter provides you with additional information about the settlement, explains FKOL’s commitments going forward, and provides you with access to information about those commitments.

On 23rd March 2021, the United States District Court for the District of Nevada accepted the criminal settlement agreed to between the U.S. Department of Justice and FKOL. The charges and resolution relate to a January 2013 FDA inspection of an FKOL active pharmaceutical (API) manufacturing plant in Kalyani India that manufactured certain APIs intended for the U.S. market. During that inspection, an FDA inspector was refused access to records in violation of the Federal Food, Drug and Cosmetic Act (“FDCA”). In addition, the criminal settlement relates to FKOL’s violations of current Good Manufacturing Practice (“cGMP”) in its manufacture of active pharmaceutical ingredients, and FKOL’s intentional concealment of records concerning these cGMP violations during that inspection of the Kalyani plant. As part of its criminal settlement, FKOL agreed to pay \$50,000,000 to the United States government. FKOL also implemented a Compliance and Ethics Program (the “Compliance Program”). In addition to FKOL’s existing FDA regulatory compliance procedures, the Compliance Program is designed to prevent, detect, and correct intentional violations of the FDCA. In particular, the Compliance Program seeks to prevent and detect intentional misconduct and intentional deviation from cGMP in the manufacturing of drugs, to prevent and detect intentional misconduct regarding the creation and maintenance of manufacturing records, and to promote transparency in all regulatory interactions with the FDA. More information about this criminal settlement may be found at the following websites:

<https://www.justice.gov/civil/consumer-protection-branch>

<https://www.justice.gov/usao-nv>

Please call FKOL’s Ethics and Integrity Helpline at 1800-102-6969 or visit us at <http://www.fresenius-kabi-oncology.com/> if you have questions about the settlement referenced above or at <https://fresenius-kabi.integritymatters.in/> (using Access Code: **FKOLINDKLY**) to report any instances in which you believe that FKOL engaged in improper conduct with respect to the manufacture or distribution of drugs. Alternatively, you may report any improper conduct associated with FKOL’s manufacture or distribution of drugs to the FDA’s Office of Regulatory Affairs at 1-888-463-6332.