DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

**CERTIFIED MAIL-RETURN RECEIPT REQUESTED**

Hospira, Inc.
Attention: Erin Wierzbicki
Senior Associate, Pfizer Global Regulatory Affairs
275 North Field Drive
Bldg. H1
Lake Forest, IL 60045

December 5, 2019

Dear Madam:

This letter is being sent under Section 506C(f) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for the reasons set forth below.

Section 506C of the FD&C Act requires a manufacturer of a drug product that is "life-supporting, life-sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition" to notify the Food and Drug Administration (FDA or the Agency) of: (1) a permanent discontinuance in the manufacture of the drug; or (2) an interruption of the manufacture of the drug that is likely to lead to a meaningful disruption[1] in the supply of that drug in the United States; and (3) the reasons for such discontinuance or interruption of manufacturing (FD&C Act § 506C(a)). The notification must be submitted at least 6 months prior to the date of the discontinuance or interruption of manufacturing, or as soon as practicable (FD&C Act § 506C(b)). Compliance with this notification requirement is essential to facilitating the mitigation or prevention of a shortage or potential shortage, and ultimately may ensure availability of critical drugs for patients.

If a person fails to submit this required notification within the required timeframe, FDA must issue a letter to that person informing the person of the failure to comply with the FD&C Act (FD&C Act § 506C(f)).

Vincristine sulfate injection is a product that is "life-supporting, life-sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition." This product is indicated for acute leukemia and has also been shown to be useful in combination with other oncolytic agents in Hodgkin's disease, non–Hodgkin's malignant lymphomas, rhabdomyosarcoma, neuroblastoma, and Wilms' tumor. It is our understanding that sometime before October 2019 there was an interruption in the manufacture of vincristine sulfate injection. This interruption was likely to lead to a meaningful disruption in the supply of this drug product in the United States. The Agency learned of the disruption from outside stakeholders on October 3, 2019, and contacted Pfizer on that date and were told by Pfizer that vincristine sulfate injection was in shortage. Pfizer provided information to post on the FDA website on

[1] The statute defines "meaningful disruption" to mean "a change in production that is reasonably likely to lead to a reduction in the supply of a drug by a manufacturer that is more than negligible and affects the ability of the manufacturer to fill orders or meet expected demand for its product," and "does not include interruptions in manufacturing due to matters such as routine maintenance or insignificant changes in manufacturing so long as the manufacturer expects to resume operations in a short period of time." (FD&C Act § 506C(h)(3)).

October 15, 2019 and the information was posted on October 16, 2019. Our records indicate that Pfizer did not notify FDA of the interruption in supply of this product. Accordingly, we are issuing you this letter to notify you of your noncompliance with the FD&C Act.

No later than thirty calendar days after the issuance of this letter, you must submit to the Agency a written response setting forth the basis for noncompliance with Section 506C and providing the required notification, including the reasons for the interruption in manufacturing that led to a disruption in the supply of vincristine sulfate injection in October 2019 (FD&C Act § 506C(f)(2)).

No later than forty-five calendar days after the issuance of this letter, FDA will make this letter and your response to the letter available to the public on FDA's Drug Shortage website, unless the Agency determines that this letter was issued in error, or, after review of your response, determines that there was a reasonable basis for noncompliance (FD&C Act § 506C(f)(3)). In posting the letter and your response on the Drug Shortage website, FDA would protect confidential commercial information and trade secrets, if any, as required by applicable law.

If you have further questions, please contact the Drug Shortage Staff at (240) 402-7770.

Please submit all communications regarding this drug product to the following address:

Drug Shortage Staff
Food and Drug Administration
WO 22, Room 6204
10903 New Hampshire Avenue
Silver Spring, MD 20993

Sincerely,

CAPT Valerie Jensen
Associate Director
Drug Shortage Staff
Center for Drug Evaluation and Research