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Important Drug Notification
Herceptin 440mg Vials and Herceptin BWFI Diluent
NDC# 50242-0134-68
List # 15534

Dear Health Care Provider:

We are writing to notify you that Genentech has received an increased number of complaints of damaged and broken vials of Herceptin 440mg and BWFI diluent, (NDC# 50242-0134-68, List # 15534). The affected vials were shipped from mid-2007 to present.

There is a risk that damaged vials may lead to a loss in sterility, which can cause infections in patients. Genentech believes the risk to patients is negligible due to a low occurrence rate and the obviousness of the affected vials. A survey of the company's adverse event surveillance systems did not indicate evidence of a change in the safety profile of Herceptin as a result of this vial damage.

Genentech has not identified any systemic error in the internal manufacturing process for Herceptin that would cause this vial damage. However, given the nature of these reports and the potential risk to patients, we request that you take the following actions for Herceptin 440mg vials and BWFI diluent prior to dispensing:

- Observe the carton for any signs of leakage, such as moisture on the carton or on the surface of the vials.
- Inspect the vials for cracks and other damage.
- Observe the vial during reconstitution as indicated in the Full Prescribing Information. When reconstituting, check for signs of loss of vacuum in the vial, e.g. syringe plunger not depressing automatically upon piercing the rubber stopper.

In the event you discover a compromised vial, do not use it for patient administration. Instead, contact Genentech Product Support at 1-800-334-0290. You will be asked to return the affected vials to Genentech, and you will receive a credit through your wholesaler.

If you have any questions, please contact Genentech Product Support at 1-800-334-0290. We appreciate your assistance in this matter and apologize for any inconvenience.

Sincerely,

Hal Barron, M.D.
Chief Medical Officer