DEPARTMENT OF HEALTH AND HUMAN SERVICES
FED OF FOOD AND DRUG ADMINISTRATION

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

1) Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not written and/or followed. Specifically,

A) You do not always follow good aseptic techniques in your [redacted] located in Plant Room [redacted] used for the manufacture of [redacted] Drug Product. The following observations were made during setup and fill operations for [redacted] Drug Product on September 1, 2020.

i. Operators' movement was not always slow, controlled and deliberate as directed in A-SOP-21-01-019, "Aseptic Technique for Parenteral Operations," rev. 15, effective date 02/24/2020, on page 2 of General Information, and on page 5 of [redacted] step [redacted].

ii. Operators were observed entering the [redacted] to perform interventions without sanitizing the [redacted] as directed in A-SOP-21-01-019, "Aseptic Technique for Parenteral Operations," rev. 15, effective date 02/24/2020; and A-SOP-21-01-042, "Aseptic Interventions in the Vial and [redacted]," rev. 35, effective date 08/31/2020.

iii. Operator(s) were observed removing [redacted] from the [redacted] by putting the [redacted] into the [redacted] of the [redacted] was in contact with the soiled [redacted]. Additionally, the storage of the [redacted] on the [redacted] during operations was in a rack where its [redacted] was not protected and it made contact with numerous non-sterile items.