DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1
Aseptic processing areas are deficient in that walls are not smooth and/or hard surfaces that are easily cleanable.

Specifically,

On 6/7/17, during inspectional tour of the ISO 7 Cleanroom area, I observed the following difficult to clean surface areas within the ISO 5 area of the (b)(4) Laminar Flow Hood:

A. Two cracks, approximately 2 inches in length, were found in the left and right plexiglass side panels inside the ISO 5 area. Each crack was found on both the left and right side panels, near the rear middle edge of the paneling, where side paneling attaches to the rear panel.

B. Two, approximately two feet in length, exposed fluorescent light bulbs and electrical wiring units, were found in both the right and left upper corners of the laminar flow hood. The lighting units were designed to be covered; however, the two covers were missing.

*DATES OF INSPECTION
6/05/2017(Mon), 6/06/2017(Tue), 6/07/2017(Wed), 6/08/2017(Thu), 6/09/2017(Fri), 6/12/2017(Mon)