OBSERVATION 1

Disinfecting agents and cleaning pads or wipes used in the ISO 5 area [aseptic processing areas] are not sterile.

The equipment and cleaning practices used at your firm pose a risk to the sterility of the drug products produced. Specifically,

The (b)(4) wipes pack kept in the ISO 7 area has a (b)(4) and is not completely sealed. The remaining unused wipes were left in the pack in the ISO 7 environment and then used for sanitizing components and product going into the ISO 5 area. (REPEAT OBSERVATION)

OBSERVATION 2

The firm lacks smoke studies performed under dynamic conditions that mimic aseptic processing conditions. Specifically,

Multiple personnel were observed producing sterile drugs in the same hood simultaneously. However, the firm's smoke study video demonstrated that only one technician performed manipulations and interventions in one hood at a time.
The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."