Appendix 1
Guidelines / Instructions for Participants

This training program is available to review, compliance and project management staff only.

Participation Prerequisites:

- Supervisory concurrence
- Must be fully able to participate for the length of the visit
- Must attend pre-site visit training
- Must have completed annual ethics training, with an emphasis on prohibitions regarding gift acceptance

If a prospective trainee is directly involved with the review or handling of any of the following with the manufacturer selected for the site visit, the prospective trainee will **not** be permitted to participate if they have:

- An IND application that is on partial or full clinical hold
- A pending BLA
- A pending efficacy supplement
- An application where compliance issues are pending
- Pending labeling supplements

If it is known, at the time of the site visit , that a prospective trainee will be assigned to a submission from the facility, the prospective trainee will be **not** permitted to participate.

Administrative Instructions

- Prepare a travel order within your office/division according to Agency requirements for travel requests.
- After returning from your site visit, submit paperwork for travel reimbursement of funds to your office/division.
- The participant's office is responsible for all travel expenses.

On-Site Guidance

- Participants are on the visit as an educational exercise. Participants should not attempt to advise the host regarding manufacturing practices nor should they attempt to "inspect" the manufacturing processes. Participants are on location to observe and learn.
- Participants must adhere to practices and procedures described by the participating firm.
- Participants should not engage in discussion or presentations regarding agency policy or policy development except for information which is already publicly available.

- Given that participating industry facilities have been qualified through a compliance review, CBER does not anticipate that its visiting reviewers would encounter areas of concern. Participants should direct any concerns or questions they might have back to CBER's Office of Communication, Training and Manufacturers Assistance (OCTMA) after the site visit for possible follow-up.