

Instructions for Sponsors for Communication of Anticipated Submissions for Inspections

*Note: Participation by the Sponsor is completely voluntary.

1. Annually, sponsors determine the anticipated facilities involved in CMC Technical Sections or prior-approval supplements.
2. Information should be submitted to the Center for Veterinary Medicine in December of each calendar year and should be in writing through general correspondence.
 - General correspondence:
 - Cover letter
 - Information is to be submitted as a .pdf file or as a hard copy
3. Information to be submitted each year:
 - Anticipated list of foreign manufacturers included in applications (originals or supplements) intended submitted for the year (January – December)
 - FEI # (if available)
 - Activities associated with each facility (e.g. Manufacturer of dosage form, Manufacturer of API, or Contract laboratory, sterilizer, etc.)
 - U.S. Agent
 - Referenced applications or master files
 - Previous inspectional history of the facility
 - See example document for suggested document structure
4. A 30 days prior notice should be submitted to the Center prior to submitting the application.
5. Changes or updates should be submitted as an amendment to the original correspondence.