The Document Required for and Inspection Procedures of Active Pharmaceutical Ingredient API (Draft)

1. Any active pharmaceutical ingredient shall be the item subject to legal inspection of imported medicaments. The obligatory inspection applicants shall submit the following documents to the inspection authority to carry out the inspection:
   (1) An application form for inspection.
   (2) A copy of medicaments permit license or other written approval issued by the central competent authority.
   (3) A copy of application for import declaration.
   (4) Necessary documents required by the central competent authority.

2. Any powdered, non-sterile APIs with the same ingredient name are subjected to randomly-selected batch examination.
3. The inspection authority will examine the randomly-selected batch by using quick-check equipment to screen narcotics. If narcotic is detected, it shall be transferred to the customs for investigation. If the quick-check equipment is unable to detect the products or drug package is not applied to the equipment, the inspection authority shall designate all products are sealed. The inspection authority shall issue a Notice of Prior for Import for custom clearance after the obligatory inspection applicant submits a storage place meeting PIC/S GMP and declares to bear the responsibility for the safety and storage of products imported with an Affidavit. FDA shall send officers to do sampling and examine the sample with quick-check equipment again. If the result is still undetermined, it shall be handled in accordance with “Pharmaceutical Good Manufacturing Practice Regulations.”
4. The storage place mentioned above is limited in one place.
5. The unselected batches for clearance shall have all inspection documents and conform to regulations.
6. Sampling ratio will be 1 out of 50 commodities/goods, or 2 out of 51 to 100 commodities/goods, or 3 out of 101 to 500 commodities/goods, or 4 out of over 1000 commodities/goods.