CHAPTER 71 - Post-Approval Monitoring of Animal Drugs, Feeds, and Devices

SUBJECT: Animal Drug Manufacturing Inspections	**IMPLEMENTATION DATE** August 04, 2006
	COMPLETION DATE Continuing

DATA REPORTING	
PRODUCT CODES	**PRODUCT/ASSIGNMENT CODES**
All Animal Drugs Industry codes: 54, 56, 68	Domestic and Foreign Inspections: 71001 (GMP) 71001A (Non-GMP) 71001B (Generic)

FIELD REPORTING REQUIREMENTS

1. Advance Notification:

As soon as the Investigator becomes aware of any significant adverse inspectional information or of a unique situation, which could result in a regulatory action (e.g. warning letter, seizure, and injunction), they should immediately inform their Supervisor. This should be done prior to issuing the Form FDA 483, Inspectional Observations, and closing out the inspection. The District's Investigations or Compliance Branch should then immediately contact by e-mail CVM/Office of Surveillance and Compliance/Division of Compliance/Enforcement and Regulatory Policy Team (HFV-232), and alert its Supervisory Team Leader of the situation. Please copy the Compliance Program Manager. Refer to the Division of Compliance's Home Page at http://www.fda.gov/AboutFDA/CentersOffices/CVM/WhatWeDo/ucm133047.htm for current contact information.

As soon as the District becomes aware of any significant inspectional, analytical, or other information developed under this program that may affect the Agency's new drug approval decisions, with respect to a firm or drug product, that information should be reported immediately via e-mail to the Supervisory Team Leader of HFV-232, the Compliance Program Manager, and ORA/ORO/OE/Division of Compliance Information and Quality Assurance (HFC-240).

2. Reporting:

For all inspections that result in the issuance of a Warning Letter, forward an electronic copy of the signed and dated Warning Letter (not redacted) via e-mail to the Compliance Program Manager. Notify the Compliance Program Manager of those firms identified as Out-of-Business (OOB) or Not Official Establishment Inventory (NOEI). Also notify HFD-095 for cancellation of their Drug Registration.

3. FACTS Reporting:

Only one inspection is required for firms manufacturing both human and animal drugs under the same control system. Time should be appropriately divided between both the human and animal compliance programs and reported into FACTS.

Charge only time spent covering the CVM regulated products against the PAC codes listed below.

A. Charge time for cGMP inspections to PAC 71001.

B. Charge time for non-cGMP investigations or inspections to PAC 71001A.

C. Charge time for cGMP inspections of generic drug manufacturers to PAC 71001B.

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PART I – BACKGROUND

A primary mission of the Food and Drug Administration is to conduct comprehensive regulatory coverage of all aspects of the production and distribution of drugs and drug products to assure that such products meet the requirements set forth under the Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act, as amended (the Act) [21 U.S.C. 301 *et seq.*]. FDA has developed two basic strategies:

1) evaluating through factory inspections, including the collection and analysis of associated samples, the conditions and practices under which drugs and drug products are manufactured, packed, tested and held, and

2) monitoring the quality of drugs and drug products through surveillance activities such as sampling and analyzing products in distribution.

This compliance program is designed to provide guidance for implementing the first strategy. Products from production and distribution facilities covered under this program are consistently of acceptable quality if the firm is operating in a state of control.

Other than the primary mission mentioned above, there are additional reasons for the Animal Drug Manufacturing Inspections Compliance Program. The first reason is the biennial inspectional requirement which ensures that manufacturing processes continue to produce safe and effective drugs. There are also concerns about the safety of the residues in meat, milk and eggs for humans and safety and effectiveness of the drug for the targeted animal if the drug is not made in compliance with Current Good Manufacturing Practice (cGMP) regulations. Similarly, the safety and efficacy of drugs described in New Animal Drug Applications (NADA)/Abbreviated New Animal Drug Applications (ANADA) cannot be assured and the applications cannot be approved unless the firm is in substantial compliance with the Act.

This version of the compliance program has been updated to reflect changes in the adverse drug experience (ADE) records and reporting requirements, as codified in 21 C.F.R. § 514.80 (effective June 30, 2003). The changes will be seen in the complaint handling section and ADE reporting sections.

The inspectional guidance found in this program is structured to provide for efficient use of resources devoted to routine surveillance coverage, recognizing that in-depth coverage of all systems and all processes is not feasible for all firms on a biennial basis. This compliance program also provides for follow-up compliance coverage as needed.

The Center for Veterinary Medicine is also responsible for the regulation of veterinary medical devices and diagnostic aids. Since CVM does not have pre-marketing approval or cGMP authority over these kinds of products, the Center relies in part on Field surveillance conducted under this program to detect violations.

PART II - IMPLEMENTATION

OBJECTIVES

The goal of this compliance program's activities is to minimize animals' exposure to adulterated drug products, and human exposure to adulterated food resulting from animals treated with adulterated drug products.

Under this program, inspections and investigations, sample collections and analyses, and regulatory or administrative follow-up are made:

1) to determine whether inspected firms are operating in compliance with applicable cGMP requirements, and if not, to provide the evidence for actions to prevent adulterated products from entering the market and as appropriate to remove adulterated products from the market, and to take action against persons responsible as appropriate;

2) to provide cGMP assessment which may be used in efficient determination of acceptability of the firm in the pre-approval review of a facility for new animal drug applications;

3) to provide input to firms during inspections to improve their compliance with regulations; and,

4) to continue FDA's unique expertise in drug manufacturing in determining the adequacy of cGMP requirements, Agency cGMP regulatory policy, and guidance documents.

STRATEGY

A. Biennial Inspection of Manufacturing Sites (includes repackaging, contract labs, etc.)

Drugs and drug products are manufactured using many physical operations to bring together components and containers and closures into a product that is released for distribution. Activities found in drug firms can be organized into systems that are sets of operations and related activities. Control of all systems helps to ensure the firm will produce drugs that are safe, have the identity and strength, and meet the quality and purity characteristics as intended.

Biennial inspections (every two years) conducted under this program:

1) reduce the risk that adulterated products are reaching the marketplace;

2) increase communication between the industry and the Agency;

3) provide for timely evaluation of new manufacturing operations in the firm; and,

4) provide for regular feedback from the Agency to individual firms on the continuing status of the firm's GMP compliance.

This compliance program applies to all animal drug manufacturing operations, with the exception of Type A medicated articles, which are covered under Compliance Program 7371.005.

Currently there are not enough FDA resources to audit every aspect of cGMP in every manufacturing facility during every inspection visit. Profile classes generalize inspection coverage from a small number of specific products to all the products in that class. This program establishes a systems approach to further generalize inspection coverage from a small number of profile classes to an overall evaluation of the firm. Reporting coverage for every profile class as defined in FACTS, in each biennial inspection, provides the most broadly resource-efficient approach. Biennial updating of all profile classes will allow for cGMP acceptability determinations to be made without delays resulting from revisiting the firm. This will speed the review process, in response to compressed time frames for application decisions and in response to provisions of the Food and Drug Administration Modernization Act of 1997 (FDAMA). This will allow for Pre-approval Inspections/Investigations Program inspections and Post-approval Audit Inspections Program inspections to focus on the specific issues related to a given application or the firm's ability to keep applications current.

The inspection is defined as audit coverage of 2 or more systems, with mandatory coverage of the Quality System (see system definitions below). Inspection options include different numbers of systems to be covered depending on the purpose of the inspection. Inspecting the minimum number of systems, or more systems as deemed necessary by the District, will provide the basis for an overall cGMP decision.

B. Inspection of Systems

Inspections of drug manufacturers should be made and reported using the system definitions and organization in this compliance program. Focusing on systems, rather than profile classes, will increase efficiency in conducting inspections because the systems are often applicable to multiple profile classes. One biennial inspection visit will result in a determination of acceptability/non-acceptability for all profile classes. Inspection coverage should be representative of all the profile classes manufactured by the firm. The efficiency will be realized because multiple visits to a firm will not be needed to cover all profile classes; delays in approval decisions will be avoided because up to date profile class information will be available at all times.

Coverage of a system should be sufficiently detailed, with specific examples selected, so that the system inspection outcome reflects the state of control in that system for every profile class. If a particular system is adequate, it should be adequate for all profile classes manufactured by the firm. For example, the way a firm handles "materials" (i.e. receipt, sampling, testing, acceptance, etc.) should be the same for all profile classes. The Investigator should not have to inspect the Material System for each profile class. Likewise in the Production System, there are general requirements like SOP use, charge-in of components, equipment identification, in-process sampling and testing which can be evaluated through selection of example products in various profile classes. Under each system there may be something unique for a particular profile class: i.e. under the Materials System, the production of Water for Injection

USP for use in manufacturing. Selecting unique functions within a system will be at the discretion of the lead Investigator. Any given inspection need not cover every system. See Part III.

Complete inspection of one system may necessitate further follow up of some items within the activities of another system(s) to fully document the findings. However, this coverage does not constitute nor require complete coverage of these other systems.

C. A Scheme of Systems for the Manufacture of Drugs/Drug Products

A general scheme of systems for auditing the manufacture of drugs and drug products consists of the following:

1. Quality System: This system assures overall compliance with cGMPs and internal procedures and specifications. The system includes the quality control unit and all of its review and approval duties (e.g., change control, reprocessing, batch release, annual record review, validation protocols, and reports, etc.). It includes all product defect evaluations and evaluation of returned and salvaged drug products. See the cGMP regulation, 21 CFR 211 Subparts B, E, F, G, I, J, and K.

2. Facilities and Equipment System: This system includes the measures and activities which provide an appropriate physical environment and resources used in the production of the drugs or drug products. It includes:

   a) Buildings and facilities along with maintenance;

   b) Equipment qualifications (installation and operation); equipment calibration and preventative maintenance; and cleaning and validation of cleaning processes as appropriate. Process performance qualification will be evaluated as part of the inspection of the overall process validation which is done within the system where the process is employed; and,

   c) Utilities that are not intended to be incorporated into the product such as heating, ventilating, and air-conditioning (HVAC), compressed gases, steam and water systems.

   See the cGMP regulation, 21 CFR 211 Subparts B, C, D, and J.

3. Materials System: This system includes measures and activities to control finished products, components, including water or gases that are incorporated into the product, containers and closures. It includes validation of computerized inventory control processes, drug storage, distribution controls, and records. See the cGMP regulation, 21 CFR 211 Subparts B, E, H, and J.

4. Production System: This system includes measures and activities to control the manufacture of drugs and drug products including batch compounding, dosage form production, in-process sampling and testing, and process validation. It also includes establishing, following, and

documenting performance of approved manufacturing procedures. See the cGMP regulation, 21 CFR 211 Subparts B, F, and J.

5. Packaging and Labeling System: This system includes measures and activities that control the packaging and labeling of drugs and drug products. It includes written procedures, label examination and usage, label storage and issuance, packaging and labeling operations controls, and validation of these operations. See the cGMP regulation, 21 CFR 211 Subparts B, G, and J.

6. Laboratory Control System: This system includes measures and activities related to laboratory procedures, testing, analytical methodology development and validation or verification, and the stability program. See the cGMP regulation, 21 CFR 211 Subparts B, I, J, and K.

The overall theme in devising this scheme of systems was the subchapter structure of the cGMP regulation. Every effort was made to group whole subchapters together in a rational set of six systems which incorporates the general scheme of pharmaceutical manufacturing operations

The organization and personnel, including appropriate qualifications and training, employed in any given system, will be evaluated as part of that system's operation. See the cGMP regulation, 21 CFR 211 Subpart B. Production, control, or distribution records required to be maintained by the cGMP regulation and selected for review should be included for inspection audit within the context of each of the above systems. See the cGMP regulation, 21 CFR 211 Subpart J. Inspections of contract companies should be within the system for which the product or service is contracted as well as their Quality System.

As this program approach is implemented, the experience gained will be reviewed to make modifications to the system definitions and organization as needed.

PROGRAM MANAGEMENT INSTRUCTIONS

A. Definitions

1. Surveillance Inspections

Surveillance Inspections are inspections conducted without prior knowledge of a violative situation.

The Full Inspection Option

The Full Inspection Option is a surveillance or compliance inspection which is meant to provide a broad and deep evaluation of the firm's cGMP. This will be done when little or no information is known about a firm's cGMP compliance (e.g., for new firms); or for firms where there is doubt about the cGMP compliance in the firm (e.g., a firm whose history has documented short-lived compliance and recidivism); or follow up to previous regulatory actions. Based on findings of objectionable conditions as listed in Part V in one or more systems (a minimum of two systems must be completed), a Full Inspection may revert to the abbreviated inspection option, with District concurrence. See Part III, Section B.1.

During the course of a Full Inspection, verification of quality system activities may require limited coverage in other systems. The Full Inspection Option will normally include an inspection audit of at least four of the systems, one of which must be the Quality System (the system which includes the responsibility for the annual product reviews).

The Abbreviated Inspection Option

The Abbreviated Inspection Option is a surveillance or compliance inspection which is meant to provide an efficient update evaluation of a firm's cGMP. The abbreviated inspection will provide documentation for continuing a firm in a satisfactory cGMP compliance status. Generally this will be done when a firm has a record of satisfactory cGMP compliance, with no significant recall, or product defect or alert incidents, or with little shift in the manufacturing profiles of the firm within the previous two years. See Part III, Section B.2. A Full Inspection may revert to an abbreviated inspection based on findings of objectionable conditions as listed in Part V in one or more systems. The Abbreviated Inspection Option normally will include an inspection audit of at least two of the systems, one of which must be the Quality System (the system which includes the responsibility for the annual product reviews). The Investigator should ensure that the optional systems are rotated in successive Abbreviated Inspections. During the course of an abbreviated inspection, verification of quality system activities may require limited coverage in other systems. Some firms participate in a limited part of the production of a drug or drug product, e.g., a contract laboratory. Such firms may employ only two of the systems defined. In these cases the inspection of the two systems will comprise inspection of the entire firm and will be considered the Full Inspection Option.

Selecting Systems for Coverage

The selection of the system(s) for coverage will be made by the District Office based on such factors as a given firm's specific operation, history of previous coverage, history of compliance, or other priorities determined by the District Office.

2. Compliance Inspections

Compliance Inspections are inspections done to evaluate or verify compliance corrective actions after a regulatory action has been taken. The coverage given in compliance inspections must be related first to the areas found deficient and being corrected.

In addition a determination must be made on the overall compliance status of the firm after the corrective actions are taken. The firm is expected to address all of its operations in its corrective action plan after a previously violative inspection, not just the deficiencies noted in the 483. The Full inspection option should be used for a compliance inspection, especially if the Abbreviated Inspection Option was used during the violative inspection.

Compliance Inspections include For Cause Inspections. The For Cause Inspections are compliance inspections which are done to investigate a specific problem that has come to the attention of some level of the Agency. The problems may be in Field Alert Reports (FARs), industry complaints, recalls,

indicators of defective products, etc. Coverage of these areas may be assigned under other compliance programs; however, expansion of the coverage to a GMP inspection (Full or Abbreviated) is to be reported under this program. For Cause Inspections may be assigned under this program as the need arises.

3. State of Control

A drug firm is considered to be operating in a state of control when it employs conditions and practices that assure compliance with the intent of Sections 501(a)(2)(B) of the Act and portions of the cGMP regulations that pertain to their systems. A firm in a state of control produces finished drug products for which there is an adequate level of assurance of quality, strength, identity and purity.

A firm is out of control if any one system is out of control. A system is out of control if the quality, identity, strength and purity of the products resulting from that system(s) cannot be assured adequately. Documented cGMP deficiencies provide the evidence for concluding that a system is not operating in a state of control. See Part V. Regulatory/Administrative Strategy for a discussion of compliance actions based on inspection findings demonstrating out of control systems/firm.

4. Drug Process

A drug process is a related series of operations which result in the preparation of a drug or drug product. Major operations or steps in a drug process may include mixing, granulation, encapsulation, tableting, chemical synthesis, fermentation, aseptic filling, sterilization, packing, labeling, testing, etc.

5. Drug Manufacturing Inspection

A drug manufacturing inspection is a factory inspection in which evaluation of two or more systems, including the Quality System, is done to determine if manufacturing is occurring in a state of control.

B. Inspection Planning

The Field will conduct drug manufacturing inspections and maintain profiles or other monitoring systems which will ensure that each drug firm receives biennial inspectional coverage, as provided for in the STRATEGY section.

The District Office is responsible for determining the depth of coverage given to each drug firm. The cGMP inspectional coverage shall be sufficient to assess the state of compliance for each firm.

The frequency and depth of inspection should be determined by the statutory obligation, the firm's compliance history, the technology employed, and the characteristics of the products. When a system is inspected, the inspection of that system may be considered applicable to all products which use it. Investigators should select an adequate number and type of products to accomplish coverage of the system. Selection of products should be made so that coverage is representative of the firms overall abilities in manufacturing within cGMP requirements.

Review of NADA/ANADA files may assist in selecting significant drug processes for coverage in the various systems. Significant drug processes are those which utilize all the systems in the firm very broadly and/or which contain steps with unique or difficult manipulation in the performance of a step. Products posing special manufacturing features, e.g., low dose products, narrow therapeutic range drugs, combination drugs, modified release products, etc., and new products made under an approved NADA/ANADA, should be considered first in selecting products for coverage.

The health significance of certain cGMP deviations may be lower when the drug product involved has no major systemic effect or no dosage limitations such as in animal products like calamine lotion or OTC medicated shampoos. Such products should be given inspection coverage with appropriate priority. Products such as animal grooming aids without drug claims should receive the lowest inspectional priority coverage.

Inspections for this compliance program may be performed during visits to a firm when operations are being evaluated according to other compliance programs, such as CDER's CPGM 7356.002 – Drug Manufacturing Inspections for all human drug products, or other investigations.

C. Profiling

The inspection findings will be used as the basis for updating all profile classes in the profile screen of the FACTS EIR coversheet that is used to record profile/class determinations. Normally, an inspection under this systems approach will result in all profile classes being updated. In the event that all profile classes cannot be covered by evaluating only two systems, then an effort should be made to expand the inspectional coverage of the firm's processing to gather enough information to update all profile classes. But if all profile classes cannot be updated, the EIR should note the reason for not updating all of the profile classes.

PART III - INSPECTIONAL

INVESTIGATIONAL OPERATIONS

A. General

Review and use the cGMPs for Finished Pharmaceuticals (21 CFR 210 and 211) to evaluate manufacturing processes. Use Guides to Inspection published by the Office of Regional Operations for information on technical applications in various manufacturing systems.

The investigator should conduct inspections according to the STRATEGY section found in Part II of this compliance program. Recognizing that drug firms vary greatly in size and scope, and manufacturing systems are more or less sophisticated, the approach to inspecting each firm should be carefully planned. For example, it may be more appropriate to review the Quality System thoroughly before entering production areas in some firms; in others, the Quality System review should take place concurrently with inspection of another system or systems selected for coverage. The complexity and variability necessitate a flexible inspection approach; one which allows the Investigator to choose the inspection focus and depth appropriate for a specific firm, but also one which directs the performance and reporting on the inspection within a framework which will provide for a uniform level of cGMP assessment. Furthermore, this inspection approach will provide for fast communication and evaluation of findings.

Inspectional Observations noting cGMP deficiencies should be related to a requirement. Requirements for manufacture of drug products (dosage forms) are in the cGMP regulation and are amplified by policy in the Compliance Policy Guides, case precedents, etc. The cGMP regulations apply to the manufacture of distributed prescription drug products, OTC drug products, approved products and products not requiring approval, as well as drug products used in clinical trials. Do not quote regulations (i.e. specific 21 CFR sections) when listing deficiencies. The cGMP regulations are not direct requirements for manufacture of Active Pharmaceutical Ingredients (API); the regulations should not be referenced as the basis for a cGMP deficiency in the manufacture of API, but they are conceptual guidance for cGMP in API manufacture. The Q7A ICH guidance document should be use for general guidance in the inspection of API manufacturers, since the scope of this document is currently limited to human drug products. Additional inspectional guidance could be found in the Center for Drug Evaluation and Research's (CDER) Compliance Program Guidance Manual 7356.002F - Active Pharmaceutical Ingredients (API) at http://www.fda.gov/downloads/ICECI/ComplianceManuals/CompliancePrograMManual/UCM125420.pdf.

Guidance documents do not establish requirements. They state examples of ways to meet requirements. Guidance documents are not to be referred to as the justification for an inspectional observation. The justification comes from the cGMPs. Current Guides to Inspection and Guidance to Industry documents provide interpretations of requirements, which may assist in the evaluation of the adequacy of cGMP systems.

Current inspectional observation policy as stated in the Investigations Operations Manual (IOM) says that

the FDA 483, when issued, should be specific, contain only significant items, and observations should be listed in order of significance. Where repeated or similar observations are made, they should be consolidated under a unified observation. Refrain from using unsubstantiated conclusions. Do not use the term "inadequate" without explaining why and how. Refer to policy in the IOM, Chapter 5, Section 512 and Field Management Directive 120 for further guidance on the content of Inspectional Observations.

Specific specialized inspectional guidance may be provided as attachments to this program, or in requests for inspection, assignments, etc.

B. Inspection Approaches

This program provides two surveillance inspectional options, Abbreviated Inspection Option and Full Inspection Option. See the definitions of the inspection options in Part II of this program.

1. Selecting the Full Inspection Option. The Full Inspection Option will include inspection of at least four of the systems as listed under the STRATEGY section in Part II, one of which must be the Quality System.

   a. Select the Full Inspection Option for an initial FDA inspection of a facility. A Full Inspection may revert to the Abbreviated Inspection Option, **with District concurrence**; based on finding of objectionable conditions as listed in Part V in one or more systems (a minimum of two systems must be completed).

   b. Select the Full Inspection Option when the firm has a history of fluctuating into and out of compliance. To determine if the firm meets this criterion, the District should utilize all information at their disposal, such as, inspection results, results of sample analyses, complaints, Three-day NADA/ANADA Field Alert Reports, recalls, etc. and the compliance actions resulting from them or from past inspections. A Full Inspection may revert to the Abbreviated Inspection Option, **with District concurrence**, based on findings of objectionable conditions as listed in Part V in one or more systems (a minimum of two systems must be completed).

   c. Evaluate if important changes have occurred by comparing current operations against the EIR for the previous Full Inspection. The following types of changes are typical of those that warrant the Full Inspection Option:

      (1) New potential for cross-contamination arising through change in process or product line.

      (2) Use of new technology requiring new expertise, significant new equipment, or new facilities.

   d. A Full Inspection may also be conducted on a surveillance basis at the District's discretion.

e. The Full Inspection Option will satisfy the biennial inspection requirement.

f. Follow up to a Warning Letter or other significant regulatory actions should require a Full Inspection option.

2. Selecting the Abbreviated Inspection Option. The Abbreviated Inspection Option normally will include inspection audit of at least two of the above systems, one of which must be the Quality System. During the course of an abbreviated inspection, verification of quality system activities may require limited coverage in other systems.

a. This option involves an inspection of the manufacturer to maintain surveillance over the firm's activities and to provide input to the firm on maintaining and improving the GMP level of assurance of quality of its products.

b. A Full Inspection may revert to the Abbreviated Inspection option, **with District concurrence**, based on findings of objectionable conditions as listed in Part V in one or more systems (a minimum of two systems must be completed).

c. An abbreviated inspection is adequate for routine coverage and will satisfy the biennial inspectional requirement.

Comprehensive Inspection Coverage

It is not anticipated that Full Inspections will be conducted every two years. They may be conducted at less frequent intervals, perhaps at every third or fourth inspection cycle. Districts should consider selecting different optional systems for inspection coverage as a cycle of Abbreviated Inspections are carried out to build comprehensive information on the firm's total manufacturing activities.

C. System Inspection Coverage

QUALITY SYSTEM

Assessment of the Quality System is conducted in two phases. The first phase is to evaluate whether the Quality Control Unit has fulfilled its responsibility to review and approve all procedures related to production, quality control, and quality assurance and assure the procedures are adequate for their intended use. This also includes the associated recordkeeping systems. The second phase is to assess the data collected to identify quality problems and may link to other major systems for inspectional coverage.

For each of the following, the firm should have written and approved procedures and documentation. The firm's adherence to written procedures should be verified through observation whenever possible. These areas are not limited only to finished products, but may also incorporate starting materials and in-process materials. These areas may indicate deficiencies not only in this system but also in other major systems that would warrant expansion of coverage. All areas under this system should be covered; however the

depth of coverage may vary depending upon inspectional findings.

- Batch production and control record review and approval prior to distribution of batches.

- Product reviews: at least annually; should include information from areas listed below as appropriate; batches reviewed, for each product, are representative of all batches manufactured; trends are identified; refer to 21 CFR 211.180(e).

- Discrepancy and failure investigations related to manufacturing and testing: documented; evaluated; investigated in a timely manner; includes corrective action where appropriate.

- Change Control: documented; evaluated; approved; need for revalidation assessed.

- Product Improvement Projects: for marketed products

- Reprocess/Rework: evaluation, review and approval; impact on validation and stability.

- Returns/Salvages: assessment; investigation expanded where warranted; disposition.

- Rejects: investigation expanded where warranted; corrective action where appropriate.

- Stability Failures: investigation expanded where warranted; need for field alerts evaluated; disposition.

- Quarantine products.

- Validation: status of required validation/revalidation (e.g., computer, manufacturing process, laboratory methods).

- Training/qualification of employees in quality control unit functions.

- Complaint reviews (quality): documented; evaluated; investigated in a timely manner; includes corrective action where appropriate.

- Complaint reviews (medical): Check the firm's written procedures describing how Adverse Drug Experience (ADE) Reports are investigated, evaluated and submitted to FDA, and determine whether they are followed.

- Check the complaint files to see whether there are any ADE complaints not submitted to FDA on FDA Form 1932 - Veterinary Adverse Reaction, Lack of Effectiveness, Product Defect Report.

- Determine if 15-Day reports, required from serious, unexpected ADEs are submitted to FDA within 15 working days.

- Complaint reviews (product defects): Examine the product defect reports submitted to FDA on FDA Form 1932. Review the information under item 19 to see if follow up actions are undertaken. For example, if it is recommended that the batch record be reviewed to assess the number of similar complaints, there should be a report indicating that the batch records have been reviewed and the complaint investigated. Further investigation of the batch records may be considered when there are repeated reports of the same type of defect.

FACILITIES AND EQUIPMENT SYSTEMS

For each of the following, the firm should have written and approved procedures and documentation. The firm's adherence to written procedures should be verified through observation whenever possible. These areas may indicate deficiencies not only in this system but also in other systems that would warrant expansion of coverage. When this system is selected for coverage in addition to the Quality System, all areas listed below should be covered; however, the depth of coverage may vary depending upon inspectional findings.

1. Facilities
   - cleaning and maintenance
   - facility layout and air handling systems for prevention of cross-contamination (e.g. penicillin, beta-lactams, steroids, hormones, cytotoxics, etc.)
   - specifically designed areas for the manufacturing operations performed by the firm to prevent contamination or mix-ups
   - general air handling systems
   - control system for implementing changes in the building
   - lighting, potable water, washing and toilet facilities, sewage and refuse disposal
   - sanitation of the building, use of rodenticides, fungicides, insecticides, cleaning and sanitizing agents
   - appropriate aseptic processing facilities, including: easily cleanable surfaces; temperature and humidity controls; air supplied through HEPA filters; environmental monitoring program, cleaning, disinfection and maintenance of facilities and equipment used to control aseptic conditions.

2. Equipment

- equipment cleaning, maintenance and use logs
- equipment installation and operational qualification where appropriate
- adequacy of equipment design, size, and location
- equipment surfaces should not be reactive, additive, or absorptive
- appropriate use of equipment operations substances, (lubricants, coolants, refrigerants, etc.) contacting products/containers/etc.
- cleaning procedures and cleaning validation
- controls to prevent contamination, particularly with any pesticides or any other toxic materials, or other drug or non-drug chemicals
- qualification, calibration and maintenance of storage equipment, such as refrigerators and freezers for ensuring that standards, raw materials, reagents, etc. are stored at the proper temperatures
- equipment qualification, calibration and maintenance, including computer qualification/validation and security
- control system for implementing changes in the equipment
- equipment identification practices (where appropriate)
- documented investigation into any unexpected discrepancy

MATERIALS SYSTEM

For each of the following, the firm should have written and approved procedures and documentation. The firm's adherence to written procedures should be verified through observation whenever possible. These areas are not limited only to finished products, but may also incorporate starting materials and in-process materials. These areas may indicate deficiencies not only in this system but also in other systems that would warrant expansion of coverage. When this system is selected for coverage in addition to the Quality System, all areas listed below should be covered; however, the depth of coverage may vary depending upon inspectional findings.

- training/qualification of personnel
- identification of components, containers, closures
- inventory of components, containers, closures
- storage conditions
- storage under quarantine until tested or examined and released
- representative samples collected, tested or examined using appropriate means
- at least one specific identity test is conducted on each lot of each component
- a visual identification is conducted on each lot of containers and closures
- testing or validation of supplier's test results for components, containers and closures
- rejection of any component, container, closure not meeting acceptance requirements. Investigate fully the firm’s procedures for verification of the source of components.
- appropriate retesting/reexamination of components, containers, closures
- first in-first out use of components, containers, closures
- quarantine of rejected materials
- water and process gas supply, design, maintenance, validation and operation
- containers and closures should not be additive, reactive, or absorptive to the drug product
- control system for implementing changes in the materials handling operations
- qualification/validation and security of computerized or automated data handling system
- finished product distribution records by lot
- documented investigation into any unexpected discrepancy

PRODUCTION SYSTEM

For each of the following, the firm should have written and approved procedures and documentation. The firm's adherence to written procedures should be verified through observation whenever possible. These areas are not limited only to finished products, but may also incorporate starting materials and in-process materials. These areas may indicate deficiencies not only in this system but also in other systems that would warrant expansion of coverage. When this system is selected for coverage in addition to the Quality System, all areas listed below should be covered; however, the depth of coverage may vary depending upon inspectional findings.

- training/qualification of personnel
- control system for implementing changes in processes
- adequate procedure and practice for charge-in of components
- identification of equipment with contents, and where appropriate phase of manufacturing and/or status
- validation and verification of cleaning/sterilization/depyrogenation of containers and closures
- calculation and documentation of actual yields and percentage of theoretical yields
- contemporaneous and complete batch production documentation
- established time limits for completion of phases of production
- implementation and documentation of in-process controls, tests, and examinations (e.g. pH, adequacy of mix, weight variation, clarity)
- justification and consistency of in-process specifications and drug product final specifications
- prevention of microbiological contamination of drug products purporting to be sterile, including the validation of any sterilization process
- prevention of objectionable microorganisms in non-sterile drug products
- adherence to preprocessing procedures (e.g., set-up, line clearance, etc.)
- equipment cleaning, maintenance and use logs

- master production and control records
- batch production and control records
- process validation, including validation and security of computerized or automated data handling system
- change control; the need for revalidation evaluated
- documented investigation into any unexpected discrepancy

PACKAGING AND LABELING SYSTEM

For each of the following, the firm should have written and approved procedures and documentation. The firm's adherence to written procedures should be verified through observation whenever possible. These areas are not limited only to finished products, but may also incorporate starting materials and in-process materials. These areas may indicate deficiencies not only in this system but also in other systems that would warrant expansion of coverage. When this system is selected for coverage in addition to the Quality System, all areas listed below should be covered; however, the depth of coverage may vary depending upon inspectional findings.

- training/qualification of personnel
- acceptance operations for packaging and labeling materials
- control system for implementing changes in packaging and labeling operations
- adequate storage for labels and labeling, both approved and returned after issued
- control of labels which are similar in size, shape, and color for different products
- finished product cut labels for immediate containers which are similar in appearance without some type of 100 percent electronic or visual verification system or the use of dedicated lines
- gang printing of labels is not done, unless these are differentiated by size, shape, or color
- control of filled unlabeled containers that are later labeled under multiple private labels
- adequate packaging records that will include specimens of all labels used

- control of issuance of labeling, examination of issued labels and reconciliation of used labels
- examination of the labeled finished product
- adequate inspection (proofing) of incoming labeling
- use of lot numbers, destruction of excess labeling bearing lot/control numbers
- physical/spatial separation between different labeling and packaging lines
- monitoring of printing devices associated with manufacturing lines
- line clearance, inspection and documentation
- adequate expiration dates on the label
- validation of packaging and labeling operations including validation and security of computerized or automated data handling system
- documented investigation into any unexpected discrepancy

LABORATORY CONTROL SYSTEM

For each of the following, the firm should have written and approved procedures and documentation. The firm's adherence to written procedures should be verified through observation whenever possible. These areas are not limited only to finished products, but may also incorporate starting materials and in-process materials. These areas may indicate deficiencies not only in this system but also in other systems that would warrant expansion of coverage. When this system is selected for coverage in addition to the Quality System, all areas listed below should be covered; however, the depth of coverage may vary depending upon inspectional findings.

- training/qualification of personnel
- adequacy of staffing for laboratory operations
- adequacy of equipment and facility for intended use
- calibration and maintenance programs for analytical instruments and equipment
- validation and security of computerized or automated data handling system

- reference standards; source, purity and assay, and tests to establish equivalency to current official reference standards as appropriate
- system suitability checks on chromatographic systems (e.g., GC or HPLC)
- specifications, standards, and representative sampling plans
- adherence to the written methods of analysis
- validation/verification of analytical methods
- control system for implementing changes in laboratory operations
- required testing is performed on the correct samples
- documented investigation into any unexpected discrepancy
- complete analytical records from all tests and summaries of results
- quality and retention of raw data (e.g., chromatograms and spectra)
- correlation of result summaries to raw data; presence of unused data
- adherence to an adequate Out of Specification (OOS) procedure which includes timely completion of the investigation
- adequate reserve samples; documentation of reserve sample examination
- stability testing program, including demonstration of stability indicating capability of the test methods

D. Sampling

Samples of defective product constitute persuasive evidence that significant cGMP problems exist. Physical samples may be an integral part of a cGMP inspection where control deficiencies are observed. Physical samples should be correlated with observed control deficiencies. Consider consulting your servicing laboratory for guidance on quantity and type of samples (in-process or finished) to be collected. Documentary samples may be submitted when the documentation illustrates the deficiencies better than a physical sample. Districts may elect to collect, but not analyze, physical samples, or to collect documentary samples to document cGMP deficiencies. Physical sample analysis is not necessary to document cGMP deficiencies.

When a large number of products have been produced under deficient controls, collect

physical and/or documentary samples of products which have the greatest therapeutic significance, narrow range of toxicity, or a low dosage strength. Include samples of products of minimal therapeutic significance only when they illustrate highly significant cGMP deficiencies.

For sampling guidance, refer to IOM, Chapter 4

E. Inspection Teams

An inspection team (See IOM 502.4) composed of experts from within the District, other Districts, or Headquarters is encouraged when it provides needed expertise and experience. Contact ORA/ORO/Division of Field Investigations if technical assistance is needed (See also FMD 142). Participation of an analyst (chemist or microbiologist) on an inspection team is also encouraged, especially where laboratory issues are extensive or complex. Contact your Drug Servicing Laboratory or ORA/ORO/Division of Field Science.

F. Reporting

The Investigator will utilize Subchapter 590 of the IOM for guidance in reporting of inspectional findings. Identify systems covered in the Summary of Findings. Identify and explain in the body of the report the rationale for inspecting the profile classes covered. Report and discuss in full any adverse findings by systems under separate captions. Add additional information as needed or desired, for example, a description of any significant changes that have occurred since previous inspections.

Reports with specific, specialized information required should be prepared as instructed within the individual assignment/attachment.

PART IV - ANALYTICAL

ANALYZING LABORATORIES

1. **Chemical Analyses** - Submit samples to the servicing laboratories as listed in Part I of the ORA workplan.

2. **Sterility** - Submit samples to the servicing laboratories noted below:

Region	Examining Laboratory
NE	NRL
SE	SRL
CE: BLT,CIN,NWJ,PHI	SRL
CE: CHI,DET,MIN	DEN
SW	DEN
PA	SAN

3. **Microbiological Examinations** - Submit samples for microbiological examination to the servicing laboratory as listed in Part I of the ORA workplan.

4. **Antibiotics Involving Microbiological Analyses** - DEN-DO will not analyze antibiotic samples that previously required certification.

5. **Bioassays** - Division of Drug Biology (HFD-170).

6. **Particulate Matter in Injectables:** NRL, SRL.

7. **Pyrogen/LAL Testing:** DEN, NRL, SAN, SRL.

ANALYSIS

Samples for routine chemical and dissolution analyses are to be examined for compliance with specifications by appropriate tests and methods (NADA/ANADA, official compendia and AOAC). Investigators will customarily collect the firm's release methodology during the inspection.

Sterility testing methods should be based on current editions of USP and the Sterility Analytical Manual. Other microbiological examinations should be based on appropriate sections of USP, AOAC, and BAM.

When the samples to be examined are not covered by NADA/ANADA and tests and methods are not available in an official compendia or AOAC, they must be analyzed by a proper FDA validated procedure.

Contact Elizabeth A. ("Beth Anne") Grove, Microbiologist (HFV-212) at (240) 276-9076 or by e-mail at elizabeth.grove@fda.hhs.gov, for additional information if there are questions about which method to use.

Forensic samples should be analyzed according to CP-7368.001. Contact the Director, Inorganic Branch (HFR-CE502), Forensic Chemistry Center, at (513) 679-2700/Ext. 181, prior to shipping samples to the Forensic Center. Keep samples for three years.

PART V - REGULATORY/ADMINISTRATIVE STRATEGY

When non-compliant conditions are identified, which demonstrate that a firm is not operating within a state of control, all voluntary, advisory, and/or judicial options currently available to the Agency should be considered. All actions, whether administrative or regulatory, should be based on patterns of significant deviations, which have been fully documented. A plan to achieve voluntary compliance should be developed on a case-by-case basis utilizing appropriate regulatory discretion before recommending an action to correct a violation. All corrective action approaches in domestic firms are monitored and managed by the District Offices. The approaches may range from shut down of operations, recall of products, conducting testing programs, development of new procedures, modifications of plants and equipment, to simple immediate corrections of conditions. CVM/OSC/Division of Compliance (HFV-230) will assist District Offices as requested.

Evidence to support a single significant deficiency or a trend of significant deficiencies within any given system or systems covered during an inspection could constitute the failure of a single system or multiple systems. The significant failure of any one system warrants consideration of an out of control determination for all of the firm's operations affected by such failure. Additionally, if one profile class fails, all profile classes affected by the same system(s) deficiencies fail. Until a firm is in compliance, any pending or future NADA/ANADA(s) affected by the system(s) failure may not be approved. When management of the firm is unwilling or unable to provide adequate corrective actions in an appropriate time frame, formal Agency regulatory actions will be recommended, designed to meet the situation encountered.

The therapeutic significance of the drug and the nature of the cGMP deviations are most important in determining an appropriate course of action. Districts may wish to consult with CVM/OSC/Division of Compliance (HFV-230) for guidance in developing compliance strategy, based on the circumstances at hand. Determining the most effective and efficient way to protect animals and the consuming public must be foremost in considering any action. The Regulatory Procedures Manual (RPM) should be consulted and followed in submitting any recommendation for regulatory action.

For example, in situations where there is no immediate risk to human or animal health and where voluntary correction should be pursued, an Untitled Letter should be used. In other situations a Warning Letter may be appropriate. The firm's response to a Warning Letter should include all actions it plans to take to achieve voluntary compliance and the time frames for completion. If this does not achieve the desired compliance result, a subsequent regulatory action (seizure/injunction) should be considered.

When the deviations are serious and/or there is reasonable likelihood of immediate risk to human or animal health, seizure should be considered. In some situations, a recall may also be appropriate. Those firms with a long history of significant repetitive and/or ongoing violations, which are unlikely to be corrected, are strong candidates for an injunction. Habitual or chronic violators may also be considered for prosecution. A combination of legal remedies may be required to check flagrant violations.

FDA laboratory tests that demonstrate effects of absent or inadequate cGMP are strong evidence for

supporting regulatory actions. Such evidence development should be considered as an inspection progresses and deficiencies are found. However, the lack of an analyzed violative physical sample is not a bar to pursuing regulatory and/or administrative action provided that cGMP deficiencies have been well documented through photos and records. Likewise, physical samples found to be in compliance are not a bar to pursuing action under cGMP charges.

Follow up to a Warning Letter or other significant regulatory actions as a result of an abbreviated inspection should warrant full inspectional coverage as defined in this program.

When deciding the type of action to recommend, the initial decision should be based on the seriousness and/or the frequency of the problem. Examples include, but are not limited to the following:

Quality System

1) Pattern of failure to review/approve procedures.

2) Pattern of failure to document execution of operations as required.

3) Pattern of failure to review documentation.

4) Pattern of failure to conduct investigations and resolve discrepancies/failures/deviations/ complaints.

5) Pattern of failure to assess other systems to assure compliance with GMP and SOPs.

Facilities and Equipment

1) Contamination with filth, objectionable microorganisms, toxic chemicals or other drug chemicals, or a reasonable potential for contamination, with demonstrated avenues of contamination, such as airborne or through unclean equipment

2) Pattern of failure to validate cleaning procedures for non-dedicated equipment. Lack of demonstration of effectiveness of cleaning for dedicated equipment.

3) Pattern of failure to document investigation of discrepancies.

4) Pattern of failure to establish/follow a control system for implementing changes in the equipment.

5) Pattern of failure to qualify equipment, including computers.

Materials System

1) Release of materials for use or distribution that do not conform to established specifications.

2) Pattern of failure to conduct one specific identity test for components.

3) Pattern of failure to document investigation of discrepancies.

4) Pattern of failure to establish/follow a control system for implementing changes in the materials handling operations.

5) Lack of validation of water systems as required depending upon the dosage form.

6) Lack of validation of computerized systems.

Production System

1) Pattern of failure to establish/follow a control system for implementing changes in the production system operations.

2) Pattern of failure to document investigation of discrepancies

3) Lack of process validation.

4) Lack of validation of computerized systems.

5) Pattern of incomplete or missing batch production records.

6) Pattern of nonconformance to established in-process controls, tests, and/or specifications.

Packaging and Labeling

1) Pattern of failure to establish/follow a control system for implementing changes in the packaging and/or labeling operations.

2) Pattern of failure to document investigation of discrepancies.

3) Lack of validation of computerized systems.

4) Lack of control of packaging and labeling operations that may introduce a potential for mislabeling.

5) Lack of packaging validation.

Laboratory Control System

1) Pattern of failure to establish/follow a control system for implementing changes in the laboratory operations.

2) Pattern of failure to document investigation of discrepancies.

3) Lack of validation of computerized systems and/or automated data collection systems.

4) Pattern of inadequate sampling practices.

5) Lack of validated analytical methodologies.

6) Pattern of failure to follow approved analytical procedures.

7) Pattern of failure to follow an adequate OOS procedure.

8) Pattern of failure to retain raw data.

9) Lack of stability indicating methods.

10) Pattern of failure to follow the stability programs.

VETERINARY MEDICAL DEVICES AND DIAGNOSTIC AIDS

CVM does not require submission of a 510(k) or formal pre-market approval for devices used in veterinary medicine. Examples of devices include such things as needles, syringes, surgical instruments, prosthetic devices, X-ray equipment, certain diagnostic test kits, dental appliances, examination gloves, sterile catheters, infusion pumps, etc.

Safety is CVM's main concern with veterinary medical devices and diagnostic aids. Some may require the prescription legend; and those intended for over-the-counter (OTC) use must bear adequate directions for use.

For suspected violative veterinary medical devices, diagnostic aids, and residue screening tests, submit labeling to CVM/OSC/Division of Compliance (HFV-230) for review and comment. FDA does have regulatory oversight over veterinary devices and can take appropriate regulatory action if a veterinary device is misbranded, mislabeled or adulterated.

See additional information on how the Agency regulates these products at the following URL: http://www.fda.gov/AnimalVeterinary/NewsEvents/FDAVeterinarianNewsletter/ucm102701.htm.

IMPORTS

See Import Alert # 68-02: "Automatic Detention of Veterinary Drugs From Firms That Have Not Met Drug GMPs."

See Import Alert # 68-09: "NEW BULK ANIMAL DRUG SUBSTANCES."

See additional information on importation of drugs at the following URL:
http://www.fda.gov/ForIndustry/ImportProgram/ucm173751.htm

EXPORTS

Section 801(e)(1) of the "FDA Export Reform and Enhancement Act of 1996" provides that unapproved new animal drugs may be exported if they meet the conditions of this section. Previously, unapproved new animal drugs were prohibited from export.

The export certificates are issued by CVM/OSC/Division of Compliance (HFV-230). The contact person is Ms. Kim E. Bell, CSO, telephone: (240) 276-9212, E-mail address: kim.bell@fda.hhs.gov. For additional information see Guidance for Industry - FDA Export Certificates at the following URL: http://www.fda.gov/RegulatoryInformation/Guidances/ucm125789.htm.

PART VI - REFERENCES AND PROGRAM CONTACTS

REFERENCES

1. Federal Food, Drug, and Cosmetic Act, as amended (the Act) [21 U.S.C. 301 *et seq.*]
2. Code of Federal Regulations, Title 21, Parts 210 and 211, as revised, including the General Comments (preamble)
3. Compliance Policy Guides Manual, Chapter 6 - Veterinary Medicine
4. Compressed Medical Gases Guideline
5. Guideline on General Principles of Process Validation
6. Guideline on Sterile Drug Products Produced by Aseptic Processing
7. Guide to Inspection of Computerized System in Drug Process
8. Regulatory Procedures Manual (RPM)
9. Investigations Operations Manual (IOM)
10. Guide to Inspections of Dosage Form Drug Manufacturers-cGMPs
11. Guide to Inspections of Lyophilization of Parenterals
12. Guide to Inspections of Pharmaceutical Quality Control Laboratories
13. Guide to Inspections of High Purity Water Systems
14. Guide to Inspections of Validation of Cleaning Processes
15. Guidance to Industry (Draft) Investigation of OOS Test Results
16. 21 CFR Part 11 Electronic Records: Electronic Signatures
17. Compliance Policy Guide7153.17 Enforcement Policy, Part 11 Electronic Records; Electronic Signatures
18. Electronic Records Guide (4/21/98) (Electronic Signatures, 21 CFR Part 11 Answers to Frequently Asked Questions)

CONTACTS

Center Contacts:

1. Questions regarding policy or requests for guidance on cGMPs, contact:

   Marea Harmon, CSO, Program Manager
   Post-Market Compliance Team, (HFV-232)
   CVM/OSC/Division of Compliance
   Telephone: (240) 276-9239
   FAX: (240) 276-9241
   E-mail Address: marea.harmon@fda.hhs.gov

2. Questions regarding guidance on New Animal Drug status of marketed drug products contact:

   Sujaya Dessai, M.S.,Team Leader (HFV- 212)
   CVM/OSC/Division of Surveillance
   Phone: (240) 276-9075
   Fax: (240) 276-9193
   E-mail Address: sujaya.dessai@fda.hhs.gov

3. Questions on product defect and adverse drug experience (ADE) reporting requirements, and the FDA Form 1932 - Veterinary Adverse Reaction, Lack of Effectiveness, Product Defect Report contact:

   John D. Baker, DVM, Division Director
   CVM/OSC/Division of Veterinary Product Safety (HFV-240)
   Phone: 240-453-6844
   Fax: 240-276-9193
   E-mail Address: john.baker@fda.hhs.gov

4. Questions regarding drug listing or registration requirements, drug shortages contact:

   Charise Kasser, CSO
   Marketed Products Information Team, (HFV-212)
   CVM/OSC/Division of Surveillance
   Telephone: (240) 276-9069
   Fax: (240) 276-9193
   E-mail Address: charise.kasser@fda.hhs.gov

5. Questions regarding guidance on regulatory action, contact:

   Marea Harmon, CSO, Program Manager

Post-Market Compliance Team, (HFV-232)
CVM/OSC/Division of Compliance
Telephone: (240) 276-9239
FAX: (240) 276-9241
E-mail Address: marea.harmon@fda.hhs.gov

6. For Program matters, contact:

Marea Harmon, CSO, Program Manager
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or

Sandra K. Washington, Industry Compliance Specialist, Program Monitor
Post-Market Compliance Team (HFV-232)
CVM/OSC/Division of Compliance
Telephone: (240) 276-9219
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E-mail Address: sandra.washington@fda.hhs.gov

ORA Contacts:

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PART VII - CENTER RESPONSIBILITIES

The Division of Compliance (HFV-230) will assess the effectiveness of this program. It will monitor, evaluate, and report on the program accomplishments.

Please send any comments on the operation and efficiency of this program to the Compliance Program Manager.