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SUMMARY

This inspection of a non-clinical laboratory was conducted as follow-up to a FY 2019, High Priority, ADUFA GLP, Directed Data Integrity assignment from Kevin Hopson, Center for Veterinary Medicine, Pre-Market Compliance and Administrative Actions (HFV-234). The inspection was conducted in accordance with the compliance program CP 7348.808, Bioresearch Monitoring-Good Laboratory Practice (Nonclinical Laboratories)", and the inspection assignment, FACTS assignment # 1240159, Operation ID #116968.

The previous inspection of this non-clinical laboratory was conducted from 02/15-03/01/2011, and was classified as "Official Action Indicated" (OAI). During that inspection, the firm was issued a 10-item Form FDA-483, "INSPECTIONAL OBERVATIONS", which cited them for the following: *Testing facility management failed to assure that all personnel clearly understood the functions they were to perform; The study director failed to assure that all applicable GLP regulations were followed; the quality assurance unit did not monitor each study to assure management that the facilities, equipment, personnel, methods, practices, records, and controls were in conformance with FDA GLP regulations; not all consulting laboratories, contractors, or grantees were notified that the study must be conducted in compliance with FDA GLP regulations; the study director failed to assure that all experimental data, including observations of unanticipated responses of the test system, were accurately recorded and*

verified; the testing facility does not have written standard operating procedures setting forth nonclinical laboratory study methods that management is satisfied are adequate to insure the quality and integrity of the data generated in the course of a study; not all nonclinical laboratory studies were conducted in accordance with the protocol; Not all individuals engaged in the conduct of or responsible for the supervision of a nonclinical laboratory study have education, training, and experience, or combination thereof, to enable that individual to perform assigned functions; testing facility management failed to assure that all test and control articles or mixtures had been appropriately tested for identity, strength, purity, stability, and uniformity, as applicable; archives failed to provide for orderly storage and expedient retrieval of all raw data, documentation, protocols, specimens, and interim and final reports. Corrective actions related to the observations were thoroughly reviewed and verified including SOP and document review during this inspection.

The current inspection assignment from CVM requested a review and data audit of a Target Animal Safety study conducted under INAD (b) (4), Study ID (b) (4) entitled "(b) (4) ", sponsored by (b) (4) (b) (4), Study Number (b) (4). Study records including raw data, correspondence and reports were reviewed. The data audit was performed through comparison of the information contained in the final report with the raw data and study protocol. No discrepancies or unreported deviations were observed.

An exit interview was held with MBR Waverly management and staff at the conclusion of this inspection on 02/01/2019. There were no objectionable conditions noted, and no Form FDA-483, Inspectional Observations was issued. Management was cooperative throughout this inspection and no refusals were encountered. Sample collection was not necessary

ADMINISTRATIVE DATA

Inspected firm:	MBR Waverly, LLC
Location:	1479 Talmadge Hill Road South Waverly, NY 14892
Phone:	607-565-3175
FAX:	607-565-7420
Mailing address:	1479 Talmadge Hill Road South Waverly, NY 14892
Dates of inspection:	1/29-2/1/2019
Days in the facility:	4

Participants: Hugh M. McClure III, Investigator

On 1/29/2019, I arrived at the MBR Waverly Production facility located at 170 SR 17C, Waverly, NY to conduct an unannounced Bioresearch Monitoring (BIMO) Good Laboratory Practice (GLP) establishment inspection. Credentials were presented and a Form FDA-482, Notice of Inspection (**Attachment 1**) was issued Ashley M. Faulk, Director of Operations and Animal Welfare Compliance who identified herself as the most responsible person onsite at the initiation of the inspection. Ms. Faulk indicated that she reports to Andy D. Smith, Executive Vice President and COO, MBR Waverly. Mr. Smith was not present at the start of the inspection but joined the inspection on 1/30/2019. Ms. Faulk was accompanied during the opening interview by Cherlyn Coddington-MacIntyre, Quality Assurance Manager, Archivist. On 1/30/2019, I arrived at the MBR Waverly facility located at 1479 Talmadge Hill Road, South, Waverly, NY where credentials were presented and a second Form FDA-482, Notice of Inspection was issued to Andy D. Smith, Executive Vice President and COO, MBR Waverly (**Attachment 2**).
This was a FY 2019, High Priority, ADUFA, Directed Data Integrity GLP assignment from the Center for Veterinary Medicine, Pre-Market Compliance and Administrative Actions (HFV-234) **(Attachment 3)** and was conducted 1/29-2/1/2019.

HISTORY

MBR Waverly, formerly Liberty Research, Inc. (LRI), is a USDA Class A licensed dealer dedicated to providing a reliable supply of high quality, barrier raised, purpose-bred, Antibody Defined (AD) Felines and Canines for use in research. MBR Waverly is comprised of two facilities one dedicated to the breeding of canines and felines for research, aka Production Site (170 SR 17C, Waverly, NY 14892) and one dedicated to research including Pilot Studies, Efficacy Studies, Safety Studies, Vaccine Trials, Duration of Immunity, Reversion to Virulence, Shed & Spread of Virus, Reproduction Studies, Animal Bio-Safety Level 2 challenges and Behavioral Toxicity (1479 Talmadge Hill Road South, Waverly, NY 14892). MBR Waverly, LLC is a separate legal entity of (b) (4)
(b) (4)
.
MBR Waverly was established on April 23, 2018 for the purpose of facilitating the Liberty Research, Inc. acquisition and was formally acquired June 1, 2018. Since the inception of MBR Waverly significant investment in facility upgrades, process improvement and quality enhancement has been initiated with the intent of operating the main production site (17C) as the breeding location to continue the supply of dogs and cats under sole ownership and control of MBR Waverly. The MBR Waverly research facility (Talmadge Hill), in the near future, (b) (4)

(b) (4)
(b) (4)
.

Normal office hours for MBR Waverly are approximately (b) (4) .
Animal care personnel work (b) (4) ,
and research personnel are present on varying schedules depending on study protocol requirements and additional responsibilities.

All correspondence related to this inspection should be addressed to:

Andy Smith, Executive Vice President and COO
MBR Waverly
1479 Talmadge Hill Road South
Waverly, NY 14892

INTERSTATE (I.S.) COMMERCE

Test and control articles used in this study were shipped/received from the sponsor, (b) (4)
(b) (4)

JURISDICTION (PRODUCTS MANUFACTURED AND/OR DISTRIBUTED)

MBR Waverly conducts FDA-regulated GLP studies for submission to the FDA in support of new animal drug research and marketing applications. Study Number (b) (4) , which was the subject of this inspection, was conducted under INAD (b) (4) .

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Information requested during this inspection was provided primarily by the following individuals:

- **Andy Smith, Executive Vice President and COO** -Mr. Smith is the most responsible individual for MBR Waverly. Mr. Smith's primary responsibilities are providing managerial support including financing, personnel, facilities and equipment to allow the Director of Operations & Animal Welfare Compliance to ensure that the MBR Waverly facilities are operating in accordance with governing laws and regulations. Mr. Smith fulfills the role of testing facility management and is responsible for the appointment Study Directors, Principal Investigators and Study Coordinators;

- **Ashley Faulk, Director of Operations (DOO) & Animal Welfare Compliance**-Ms. Faulk reports directly to Mr. Smith and is responsible for oversight and coordination of facility operations and management of Production Site staff to ensure compliance with applicable laws and regulations. Additionally, Ms. Faulk provides support to Veterinary Services and Attending Veterinarian.
- **Cherylyn Coddington-MacIntyre, Quality Assurance Manager-**Ms. Coddington-MacIntyre supports the DOO by monitoring facility operations for compliance with applicable laws and regulations. She oversees the execution of the Marshall Farms Quality Management System through web and paper-based document control, staff training, and facility inspections to assure compliance with facility SOPs and applicable state and federal regulations.
- **Tina Yanchis-Kirby, Regulatory Compliance and Quality Assurance Director-**Ms. Yanchis-Kirby reports directly to Andy Smith. She has directed study regulatory activities at both the MBR Waverly Production and Research sites. Her responsibilities include facility and study operations monitoring and reporting findings/issues to Site Director and Test Facility Management. She provides document control, scheduling equipment calibration and preventative maintenance. She conducts contractor compliance assessments for those used in the support of GLP studies conducted at the facility.

Other MBR Waverly staff members that met with me and/or provided information include: (b) (6) (b) (6) Veterinary Services and Archivist; (b) (6), Training Manager and Assistant Study Coordinator; Maranda Lawton, IACUC Chair; and Tanya Shaffer, Director of Operations (Research Site) and Study Coordinator.

A copy of the organizational charts for MBR Waverly attached as **Exhibit 1**.

DATA AUDIT

As part of this inspection, I conducted a records review/data audit for (b) (4) study number (b) (4) (b) (4):

"(b) (4) "

This GLP Target Animal Safety study was sponsored by (b) (4) (b) (4). The study was conducted by (b) (4). under a Laboratory Services Master Agreement with the sponsor dated 10/28/2014 and a Study-Specific Addendum dated 5/6/2015 (see **Exhibit 2**). The objective of the study was to assess the safety of this (b) (4)). All animals ((b) (4) male and (b) (4) female domestic short hair cats) (b) (4) with approximately (b) (4), by

(b) (4) prior to test article administration. (b) (4) cats were randomly assigned to three study groups;(b) (4)

Dosing Schedule:

Group No	No. Animals	Treatment Dose	Treatment route, Frequency	Monitoring Period
1	(b) (4)		Topical, one dose, Study Day 0	91/92 Days
2	(b) (4)		Topical, one dose, Study Day 0	91/92 Days
3	(b) (4)		Topical, one dose, Study Day 0	91/92 Days

This study was initiated on 1/20/2016 with the study director (b) (6)) signature/date of the study protocol and concluded on 12/15/2017 with the signature/date of the study director on the final report. The final report was amended (Amendment 1) by the study director on 5/18/2018. The study protocol and amendments that were present in the study files were identical to those attached to the final report provided to FDA by the sponsor and included in the inspection assignment background material. The study was approved by the facility IACUC on 5/19/2015 and as part of this inspection, the IACUC SOP (FAC.1100.002, Institutional Animal Care and Use Committee), and the minutes for the IACUC's

most recent meeting on 7/26/2018 were reviewed. The IACUC SOP and meeting minutes are attached as **Exhibit 3.**

The animals used in this study (b) (4) male and (b) (4) female domestic short hair cats) were transferred from the production site (MBR Waverly 17C) and were received at the testing facility (MBR Waverly, Talmadge Hill) on 5/26/2015. The pre-study period began on 5/27/15 and lasted until 2/2/2016, the beginning of study acclimation period (study day -14). Study animals were (b) (4) with the (b) (4)) during the pre-study period on 6/3/2015. The test article (Batch #(b) (4) (b) (4)) was received at the facility on 2/2/2016 from the sponsor. The control article (b) (4) was received at the test site on 2/3/2016. Reserve samples of the test and control articles were collected and retained as required.

The in-life phase of the study began on 2/16/2016 (Study 0) with the administration of the of the test and control articles and ended on 5/18/2016 with the completion of the study day (b) (4) necropsies. Blocks and slides as required by the study protocol were prepared by the histology lab. Histopathological assessment was performed by a pathologist from (b) (4) .
As part of this inspection, a block/slide comparison was performed for gross lesions that were found at necropsy and histopathologically evaluated with no discrepancies noted.

I reviewed records for Study Number (b) (4) including the protocol and amendments, animal records, raw data, equipment records, test article records, laboratory analyses, and associated SOPs. I reviewed animal history records for receipt of the animals, physical examinations and laboratory analyses. Animals selected for the study met the protocol inclusion criteria prior to randomization (Study Day -1, 2/15/2016).

Comparison of the final report that accompanied the inspection assignment with that found in the study records revealed no discrepancies. Statements of the final report were compared with the protocol requirements, raw data and contributing scientist reports. The records reviewed include animal receipt and acclimation; test/control article characterization, receipt, dispensation, dosing, accountability and disposition; body weights; water/feed analysis; equipment maintenance and calibration; environmental controls; blood sampling, clinical pathology (hematology, blood chemistries and coagulation); heartworm antigen/microfilaria testing; toxicokinetics/bioanalysis, clinical observations; euthanasia; necropsy, and histopathology. There was no indication that the protocol blinding/masking requirements were compromised at any time during the study. No objectionable conditions were noted.

As part of this inspection, training records for the study director and study staff were reviewed and found that all staff received GLP training at their initial employment and yearly thereafter. The study director and staff were all qualified to perform their assigned tasks associated with the execution of the study

protocol. Additionally, I requested the facility's Master Schedule covering 2016, 2017, and 2018 (see **Exhibit 4**). My review of the Master schedule revealed that the study director's workload was appropriate and manageable. It was also noted that all contractors/contributing scientists utilized during this study were informed of the GLP status of the study and those contractors were inspected/audited by the LRI/MBR Waverly Quality Assurance Unit (QAU). Inspections/audits were performed by the QAU either by on-site visits or by remote records audits (see **Exhibit 5**) and for most contractors on-site or remote audits are performed every other year.

REFUSALS

No refusals were encountered during this inspection.

GENERAL DISCUSSION WITH MANAGEMENT

At the conclusion of this inspection, an exit interview was held with management and staff. In attendance were: Andy Smith, Executive Vice President & COO; (b) (6), Study Coordinator; (b) (6), Training Manager, Assistant Study Coordinator; Dr (b) (6), DVM, Research Site Attending Veterinarian; Maranda Lawton, IACUC Chair; Tanya Shaffer, Director of Operations (Research Site), Study Coordinator; Tina Yanchis-Kirby, Regulatory Compliance & Quality Assurance Director. By phone: Cherylyn Coddington-McGuire, Quality Assurance Manager (Production Site); Ashley Faulk, Director of Operations & Animal Welfare Compliance (Production Site); and (b) (6), Archivist.

No objectionable conditions were noted and no FDA-483, Inspectional Observations was issued.

SAMPLES COLLECTED

No samples were collected.

EXHIBITS COLLECTED

1. Organizational Charts for MBR Waverly
2. Laboratory Services Master Agreement and Study-Specific Addendum dated.
3. IACUC SOP and Meeting Minutes.
4. Master Schedule Covering 2016, 2017, and 2018.
5. QAU Contractor/Contributing Scientist Audit History.

ATTACHMENTS

1. Form FDA-482, Notice of Inspection Dated 1/29/2019.
2. FDA-482, Notice of Inspection Dated 1/30/2019.
3. Inspection Assignment Dated 12/11/2018.

Hugh M. Mcclure Iii -S

Digitally signed by Hugh M. Mcclure Iii -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300053674, cn=Hugh M. Mcclure Iii -S
Date: 2019.03.01 15:41:07 -05'00'

Hugh M. McClure III, Investigator/National Expert

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

1. DISTRICT OFFICE ADDRESS & PHONE NO.
200 Chestnut St. (215) 597-4390
Rm 900
Philadelphia, PA 19106

TO

2. NAME AND TITLE OF INDIVIDUAL
Ashley M. Faulk, Dir. of Operations and Animal Welfare Compliance

3. DATE
1/29/19

4. FIRM NAME
MBR Waverly

5. HOUR
9:55 a.m.
p.m.

6. NUMBER AND STREET
170 St Rt. 17C

7. CITY AND STATE & ZIP CODE
Waverly, NY 14892

8. PHONE NO. & AREA CODE
(607) 565-8131

Notice of Inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetics Act [21 U.S.C. 374(a)][1] and/or Part F or G, Title III of the Public Health Service Act [42 U.S.C. 262-264][2]

As a small business that is subject to FDA regulation, you have the right to seek assistance from the U.S. Small Business Administration (SBA). This assistance includes a mechanism to address the enforcement actions of Federal agencies. SBA has a National Ombudsman's Office that receives comments from small businesses about Federal agency enforcement actions. If you wish to comment on the enforcement actions of FDA, CALL (888) 734-3247. The website address is www.sba.gov/ombudsman.

FDA has an Office of the Ombudsman that can directly assist small business with complaints or disputes about actions of the FDA. That office can be reached by calling (301) 796-8530 or by email at ombuds@oc.fda.gov.

For industry information, go to www.fda.gov/oc/industry.

9. SIGNATURE(S) *(Food and Drug Administration Employee(s))*	10. TYPE OR PRINT NAME(S) AND TITLE(S) *(FDA Employee(s))*
Hugh M. McClure III	Hugh M. McClure III, CSO, NEX

[1] Applicable portions of Section 704 and other Sections of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] are quoted below:

Sec. 704(a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, tobacco products, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, tobacco products, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports foods, the inspection shall extend to all records and other information described in section 414, when the standard for records inspection under paragraph (1) or (2) of section 414(a) applies, subject to the limitations established in section 414(d). In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products are manufactured, processed, packed, or held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this

(Continued on Reverse)

of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession."

Part F – * * * * * *Control of Radiation.

Sec. 360 A (a) "If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times any area in such factory, warehouse, or establishment in which the manufacturer's tests (or testing programs) required by section 358(h) are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this subpart and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 359(a)(2) or 359(e)."

(b) "Every manufacturer of electronic products shall establish and maintain such records (including testing records), make such reports, and provide such information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this subpart and standards prescribed pursuant to this subpart and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records, and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to section 359(a)."

* * * * * *

(f) "The Secretary may by regulation (1) require dealers and distributors of electronic products, to which there are applicable standards prescribed under this subpart and the retail prices of which is not less than $50, to furnish manufacturers of such products such information as may be necessary to identify and locate, for purposes of section 359, the first purchasers of such products for purposes other than resale, and (2) require manufacturers to preserve such information. Any regulation establishing a requirement pursuant to clause (1) of the preceding sentence shall (A) authorize such dealers and distributors to elect, in lieu of immediately furnishing such information to the manufacturer to hold and preserve such information until advised by the manufacturer or Secretary that such information is needed by the manufacturer for purposes of section 359, and (B) provide that the dealer or distributor shall, upon making such election, give prompt notice of such election (together with information identifying the notifier and the product) to the manufacturer and shall, when advised by the manufacturer or Secretary, of the need therefore for the purposes of Section 359, immediately furnish the manufacturer with the required information. If a dealer or distributor discontinues the dealing in or distribution of electronic products, he shall turn the information over to the manufacturer. Any manufacturer receiving information pursuant to this subsection concerning first purchasers of products for purposes other than resale shall treat it as confidential and may use it only if necessary for the purpose of notifying persons pursuant to section 359(a)."

* * * * * *

Sec. 360 B.(a) It shall be unlawful–

(1) * * *

(2) * * *

(3) "for any person to fail or to refuse to establish or maintain records required by this subpart or to permit access by the Secretary or any of his duly authorized representatives to, or the copying of, such records, or to permit entry or inspection, as required or pursuant to section 360A."

* * * * * *

Part G - Quarantine and Inspection

Sec. 361(a) "The Surgeon General, with the approval of the Secretary, is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

1. DISTRICT OFFICE ADDRESS & PHONE NO.
200 Chestnut St. Rm 900
Philadelphia, PA 19106
(215) 597-4390

TO

2. NAME AND TITLE OF INDIVIDUAL
Andy D. Smith, Executive Vice President and COO

3. DATE
11/30/19

4. FIRM NAME
MBR Waverly

5. HOUR
9:40 a.m.
p.m.

6. NUMBER AND STREET
1479 Talmadge Hill Rd. South

7. CITY AND STATE & ZIP CODE
Waverly, NY 14892

8. PHONE NO. & AREA CODE
(607) 565-3175

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For industry information, go to www.fda.gov/oc/industry.

9. SIGNATURE(S) *(Food and Drug Administration Employee(s))*	10. TYPE OR PRINT NAME(S) AND TITLE(S) *(FDA Employee(s))*
Hugh M. McClure III	Hugh M. McClure III, CSO

[1] Applicable portions of Section 704 and other Sections of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] are quoted below:

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of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession."

Part F – * * * * * *Control of Radiation.

Sec. 360 A (a) "If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times any area in such factory, warehouse, or establishment in which the manufacturer's tests (or testing programs) required by section 358(h) are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this subpart and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 359(a)(2) or 359(e)."

(b) "Every manufacturer of electronic products shall establish and maintain such records (including testing records), make such reports, and provide such information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this subpart and standards prescribed pursuant to this subpart and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records, and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to section 359(a)."

* * * * * *

(f) "The Secretary may by regulation (1) require dealers and distributors of electronic products, to which there are applicable standards prescribed under this subpart and the retail prices of which is not less than $50, to furnish manufacturers of such products such information as may be necessary to identify and locate, for purposes of section 359, the first purchasers of such products for purposes other than resale, and (2) require manufacturers to preserve such information. Any regulation establishing a requirement pursuant to clause (1) of the preceding sentence shall (A) authorize such dealers and distributors to elect, in lieu of immediately furnishing such information to the manufacturer to hold and preserve such information until advised by the manufacturer or Secretary that such information is needed by the manufacturer for purposes of section 359, and (B) provide that the dealer or distributor shall, upon making such election, give prompt notice of such election (together with information identifying the notifier and the product) to the manufacturer and shall, when advised by the manufacturer or Secretary, of the need therefore for the purposes of Section 359, immediately furnish the manufacturer with the required information. If a dealer or distributor discontinues the dealing in or distribution of electronic products, he shall turn the information over to the manufacturer. Any manufacturer receiving information pursuant to this subsection concerning first purchasers of products for purposes other than resale shall treat it as confidential and may use it only if necessary for the purpose of notifying persons pursuant to section 359(a)."

* * * * * *

Sec. 360 B.(a) It shall be unlawful–

(1) * * *

(2) * * *

(3) "for any person to fail or to refuse to establish or maintain records required by this subpart or to permit access by the Secretary or any of his duly authorized representatives to, or the copying of, such records, or to permit entry or inspection, as required or pursuant to section 360A."

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Part G - Quarantine and Inspection

Sec. 361(a) "The Surgeon General, with the approval of the Secretary, is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary."