UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SCAN AND EMAIL
CONFIRMATION OF RECEIPT REQUESTED

Mr. John Doe
Happy Farm Research
123 Merry Lane
Bright, AS 45678
(987) 654-3210
doejohn@happyfarmresearch.gov

November 23, 2022

Dear Mr. Doe:

This is to inform you that the Environmental Protection Agency (EPA) will conduct a Good Laboratory Practice (GLP) Inspection at your facility under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

The inspection will be conducted during the week of December 1, 2022. The inspection will be led by Jane Dear. The inspection team will review your facility's compliance status with the EPA FIFRA GLP regulations, 40 Code of Federal Regulations (CFR) Part I 60 and will audit those aspects of the studies listed in Attachment I performed by Happy Farm Research.

In addition, the inspection team will choose one or more completed or ongoing studies from your Master Schedule foraudit.

The purpose of study audits is to validate data in final reports which have been presented to the EPA in support of a registration or marketing petition under FIFRA.

The purpose of the compliance review is to determine that the GLP regulations of FIFRA are being observed in your testing facility's current procedures and practices for pertinent studies being conducted.

Please note that under the FIFRA GLP regulations at 40 CFR 1 60.1 5(b) EPA will not consider reliable for purposes of supporting a FIFRA application for a research or marketing permit any data developed by a testing facility that refuses to permit inspection.

To successfully conduct our inspection, we request that the following matters be addressed prior to our arrival at Happy Farm Research.

Please make available suitable space for the team. Please have available and in good order all original data needed to verify the final report of each study, along with full copies of the protocol (including protocol amendments) and all reports submitted by your facility to the study sponsor. All current personnel who were associated with these studies should be available for discussion with members of the team as necessary. The inspection team will need for review copies of all Standard Operating Procedures (SOP) documents in use at the time of study.

We will require very specific information at your facility regarding the test substance. This includes, but is not necessarily limited to, the source and lot number, analysis for purity and identification, record of receipt, and storage, usage data, test substance inventory logs and custodial procedures for each test substance.

In addition , please obtain a statement from the sponsor indicating the origin of the test substance, namely , if it was sampled from a batch for contemporary commercial use or was synthesized or manufactured for the specific study for which the raw data are being audited . In either case, the statement should include chemistry data, i. e., all data to prove the identity and purity of the test substance , the identity of any and all impurities detected by sponsor or manufacturer, and data to prove storage stability of the test substance during the lifetime of the study.

As part of EPA's commitment to small businesses, EPA advises small businesses of their right under the Small Business Regulatory Enforcement Fairness Act (SBREFA) to comment to the SBA's National Ombudsman about the agency' s regulatory enforcement activities . The EPA has a longstanding practice of using the Information Sheet to notify small businesses of this right and provide important information that may assist small businesses in identifying and complying with environmental requirements (see Enclosure).

Additionally, the Information Sheet reminds readers that SBREFA does not relieve a small business of its responsibility to respond in a timely manner to an information request, administrative or civil complaints or other enforcement actions or communications, nor does it create any new rights or defenses under the law. The sheet also explains that SBREFA does not affect the EPA' s ability to protect public health or the environment under any of the environmental statutes that the EPA enforces, including the right to take remedial or emergency response action when appropriate.

If there are any questions arising from this notice, please feel free to call me directly. Under ordinary conditions the dates selected for the inspection will not be changed. I may be reached during regular hours at (202) 564-2365.

Sincerely,

Digitally signed by Fair All

Fair All

Fair All, Director
Good Laboratory Practice Program

Enclosure

Attachment I

STUDY AUDITS

1) Study: Cyflumetofen: Magnitude of the Residue on Squash (Summer)

   Lab Proj. No.: N/A

   MRID: 52003003

2) Study: Cyflumetofen: Magnitude of the Residue on Pepper (Bell and Non-Bell)

   Lab Proj. No.: N/A

   MRID: 52003004

3) Study: Isocycloseram ISM-555 – Magnitude of the Residue on Peanut Final Report

   Lab Proj. No.: N/A

   MRID: 51228328

4) Study: Fluazinam: Magnitude of the Residue on Tomato

   Lab Proj. No.: N/A

   MRID: 50903902