

# **Petitioner AMVAC**

## **Exhibit 46**

# **Suspension SOP**

## **Revised April 8, 2009**

**Background and Purpose:** As a result of (1) OECA terminating its role in OPP's suspension process and (2) the approved redelegation from OPPTS senior management, SRRD has developed the following SOP to manage suspensions for failure to submit studies in response to the Data Call In (DCI).

### **Phase 1**

- The CRM contacts the registrant by certified letter to inform them that suspension action is imminent if the data are not submitted immediately;
- The CRM identifies suspension candidates and provides the SRRD Suspension Coordinator with the materials listed below to prepare the Notice of Intent to Suspend (NOITS) letter and attachments.
  1. Chemical Name
  2. Company Name, Address and Company Contact
  3. Product Registration Number
  4. Product Name
  5. DCI Information (issuance date, guideline no./name and due date of missing data)
  6. Correspondence and Telephone Logs
- Suspension Coordinator prepares Attachment I-II, Federal Register Notice (FRN), and the NOITS letter. The designated CRM prepares Attachment III
  1. Attachment I: The products affected by the NOITS (can include more than one company). The attachment lists the registration number and product names.
  2. Attachment II: Listing of outstanding data by guideline number and name;
  3. Attachment III: Explanatory narrative provides the history of SRRD efforts to effectively communicate with the registrant requesting submission of data. In addition copies of green card postal receipts, telephone logs, and correspondence between the Agency and registrants.
  4. The FR Notice includes the letter to the registrant, tables listing the registrant(s) and their product(s), the data required and not submitted by the registrant, and the explanatory appendix (III).

### **Phase 2**

- The NOITS letter (w/attachments) and FRN are sent to OGC for concurrence.
- Approved suspension package are sent to the OPPTS FR office for publication processing.
- SRRD Division Director signs the OGC approved NOITS letter and FRN.

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- The NOITS letter is sent to the registrant by SRRD via certified mail return receipt.
- FR document and attachments are sent LaTanya Moody who will load document into FDMS.
- If the registrants do not respond within 30 days from receipt of the NOITS letter and data are not submitted nor a hearing requested, their registrations are legally suspended for the products listed in the NOITS letter (Two weeks after the 30 day time period, the Suspension Coordinator should contact OGC to verify that a hearing has not been requested).

### **Phase 3**

- SRRD will notify John Jamula (ITMRD) to enter into OPPIN that the product(s) is suspended (providing registration no. and suspension effective date).
- SRRD will notify Les Hoot (ITMRD) to post onto the web page the list of currently suspended products (providing Chemical name, Company Name/Company Contact, Registration No., Product Name, Suspension Effective Date). [OECA will help in getting the word out to the regions and states about the web page's existence.]
- If the required data are received by SRRD, the Suspension Coordinator will send the registrant a letter notifying them that the suspension has been lifted.
- SRRD will update OPPIN to reflect that the suspension has been lifted.
- SRRD will notify Les Hoot to update the web site by removing that product to reflect that the suspension has been lifted.