IR-4 Advisory #2003-04

Title: **Test/Reference Substance Container Labels – Required Information**

Issues/ Questions: What should be done if information such as expiration date and storage conditions do not appear on the test/reference substance container label, but 1) documentation from the registrant includes this information, or 2) the container label and the registrant documentation do not include this information?

Background: In recent EPA inspections of IR-4 field test sites, auditors have noted that expiration dates were not indicated on all containers of test substance. Expiration date (if any) and storage conditions (where appropriate) are items required on test/reference substance container labels (along with the substance name, CAS or code number, and batch number), per the Good Laboratory Practice Standards 40 CFR 160.105(c).

1) Study personnel are not always transcribing the expiration date or storage conditions from registrant documentation onto a test/reference substance container, if this information was not included on the container label by the registrant.
2) In some cases, study personnel follow the old practice (captured in some SOPs) of assigning an "arbitrary" expiration date (based on receipt date) or assuming storage conditions when this information is not provided in the registrant documentation or on the container label.

Resolutions: 1) **REMINDER!** When the expiration date and/or storage conditions (or the substance name, CAS or code number, and batch number) are included in the registrant documentation, but have not been included on the container label by the registrant, study personnel should transcribe this information onto the test/reference substance container. If there is insufficient space on the container label for the required information, another label may be attached to the container, as long as the additional label does not obscure any information on the original label. Remember to initial and date entries! On Part 4A of the FDB, or in the lab study file, identify the source of the information as "provided on documentation from the registrant."

2) Upon receipt of test/reference substance with missing label information (name, CAS or code number, batch/lot number, expiration date, storage conditions) on the container or in the registrant documentation, study personnel should not arbitrarily assign any of this information. Contact the Study Director (SD) immediately to obtain the missing information from the registrant. The SD is responsible for providing the missing information to pertinent study personnel in a timely manner. On Part 4A of the FDB, or in the lab study file, the source of the information can be identified as "obtained by the SD/IR-4 HQ/lab personnel from the registrant," and the communication should be inserted into the FDB or study file.

(Reminder: Issue 2 above was generically addressed in Items 42 & 44 in the San Antonio Results Document, dated 9/27/02: "contact the SD if inadequate information is received")

If you have any questions, please contact your Regional/ARS Field Coordinator or the appropriate Study Director for further guidance.