Attachment 4

PRIVATE LABORATORY PACKAGE REVIEW GUIDE

1. SAMPLING

a. Lot is described.
b. Sample is collected randomly.
c. Sample is collected from sufficient number of cartons (proper distribution).
d. Proper size sample is collected.
e. Sufficient number of subs are collected.
f. Collection is documented/collector is identified.

2. SAMPLE DATA

a. Sample number on worksheet relates to final report.
b. Sample is accurately described and relates to invoice (e.g. dimensions for ceramic ware, size of fish, shrimp, etc.).
c. Contents of each sub composited (or portion taken, if whole sub).
d. The correct portion of composite is taken and weight is shown.
e. Where individual subs are analyzed, the correct number of subs examined.
f. Sample is correctly prepared.
g. Sample is correctly stored e.g. temperature.
h. Label is submitted if present on the product.

3. ANALYTICAL METHOD

a. The correct method is used and cited. Non-official methods are validated. Current versions of official methods are used.
b. Each step of the method is followed.
c. Deviations from official method are explained and validated.
d. Use of special reagents and equipment is described.
e. All equipment is identified to be traceable to its QA records.
f. No unresolved analytical problems are evident.
g. All analytical attempts are included and discarded results are explained.
h. Recovery and blank data are acceptable.
i. Calculations are clear, accurate, and easy to follow.
j. All raw data, including chromatograms and spectra and reproductions of TLC plates, are submitted, as well as print-outs of reader instruments, e.g. Vidas.
k. Laboratory conclusions are supported by analytical results.
l. All analysts sign worksheet and 'who did what' is clearly indicated. 'When' can also be determined as called for by the method (e.g. for microbiological analysis).

4. STANDARD DATA

a. Source of standard is cited.
b. Preparation dates *and* preparer of primary and working standards are cited.
c. Weights, dilutions, and concentrations of standard materials are documented.
d. Standard curve has the correct number of points; sample results are within the limits of the standard curve.
e. Standard curve submitted unless regression analyses used to calculate sample results.
f. Standard and/or blank injections bracket sample injection, as needed.

5. INSTRUMENT PARAMETERS

The following parameters are documented:

a. Name & model of instrument, accessories used
b. Parameters for operation of instrument
c. Wavelength used
d. Lamp power settings
e. Type of flame used
f. Column type, i.d., and length used
g. Gas/Liquid phases med
h. Flow rates
i. Detector and mode used
j. Temperature settings
k. Attenuation
l. Chart speed

6. CONDOMS/GLOVES

a. Sample is of a single type and brand.
b. Proper sample size is collected and examined according to method, and is of scheduled number to be examined (lots, glove size, use).
c. Label is reviewed.

7. MICROBIOLOGICAL ANALYSIS

a. Batches of media are identified with QA numbers.
b. Positive and negative controls traceable to reference cultures are run concurrently with sample analysis and carried through until the sample is completed. Controls are within range for a valid assay.
c. Refrigerators, freezers and water baths are identified on the worksheet.
d. Biochemical reactions/patterns are obtained in the analysis.
e. Expired media, reagents or test kits are not used in the analysis.
f. FDA guidelines followed on such items as number of colonies to pick.

g. Each step of the method is followed, with media, incubation temperatures, amounts transferred, etc. being documented.

To be confirmed during on-site assessment visits:

a. Media used in microbiological analysis undergoes QA checks for pH, sterility, and growth promotion.
b. Batches of media have expiration dates.
c. Batches of media are traceable to autoclaves and autoclave runs.
d. Autoclave processing cycles are validated with biological indicators.
e. Refrigerator, freezer, and water bath temperatures are monitored daily.
f. Laboratory grade water, free from traces of dissolved metal, bactericidal, and inhibitory compounds is used to prepare media, reagents, and dilution blanks.

8. PERSONNEL

Analyst CV's are on file or are submitted with worksheet packages. CV's should include analyst's training or experience or both in the areas covered by the analysis.