APPENDIX II: Laboratory Information Bulletin Format

Title

Author(s)/Affiliation-The main contact for the work should be identified by an asterisk or number. An e-mail address or phone # for the main author should be provided. In case the authorship includes Non-FDA persons, a consent letter (e-mail) from that author would be appropriate.

Abstract-An abstract should provide a condensed version of the method, describing the major concerns and scope of the article. This should be about one paragraph long.

The special **ADMINSTRTION NOTE** must be added on the first page of every Laboratory Information Bulletin (LIB).

The Laboratory Information Bulletin is a tool for the rapid dissemination of laboratory methods (or information) which appear to work. It may not report completed scientific work. The user must assure him/her by appropriate calibration procedures that LIB methods and techniques are reliable and accurate for his/her intended use. Reference to any commercial materials, equipment, or process does not in any way constitute approval, endorsement, or recommendation by the Food and Drug Administration.

Since LIBs will be submitted electronically and posted on the DFS web site they need to be 508c compliant.

Section 508c of the Rehabilitation Act of 1978 as amended: Section 508 (508 statute html, 508 statute pdf) requires that Federal agencies' electronic and information technology is accessible to people with disabilities, including employees and members of the public.

Section 508 establishes requirements for any electronic and information technology developed, maintained, procured, or used by the Federal government. The term "electronic and information technology" has been defined by the Access Board in regulations published December 21, 2000. Section 508 exempts national security systems from its requirements.

Information regarding all aspects of assistive technologies and accessibility under Section 508 is available at the federal government's official website, http://www.section508.gov/.

This includes charts, figures, tables, pictures, text, hyper links.

Introduction- This should be approximately one or two paragraphs providing background information on FDA's concern and interest into the development of this method/method change.

Experimental- Although this section should be as complete as possible, author(s) should be careful about product and manufacturer names. For example, under method development we may use commercial kits and compare kits from multiple manufacturers. Some of these kits may be regulated products. The data may suggest that a kit does not meet labeling claims or one kit is better than the competitors. LIBs are reports of experimental data. They are not the route for taking regulatory action. Action cannot be taken, because the method is not official; that is, under development. We cannot set policy through LIBs. This would also be true when developing methodology to determine the effectiveness of products. The author(s) should code the reagent/equipment. Author(s) should also identify any deviations if the product is not used as labeled. Deviations can impact limits of detection, limits of quantitative, linearity, ruggedness.

Use of official samples should be avoided as much as possible. In case we need to use official samples, bacterial isolate, care should be adopted to remove original number/designation to protect confidentiality.

This area should be divided into the following basic areas:

Equipment- list of all equipment to perform the method and sources
Reagents- list of all reagents used in the method and sources
Procedures:
Instrument Parameters– provide wavelengths, temperatures
Standard Preparations-describe dilution schemes
Sample Preparations- describe extractions, spiking, special handling and dilutions
Data-provide charts or graphics of the data collected from the experimentation. Summary data can be provided depending on the amount of data collected. Presentation should be concise to make interpretation easy to view.
Statistical Evaluation – author(s) should identify the statistical method, the null hypothesis, the planned comparisons, unplanned comparisons, and the acceptance level. Unplanned comparisons lose a degree of freedom. The number of replicates need to obtain the statistical power should be predetermined.

Results and Discussion-This can be several paragraphs discussing the conclusions that can be drawn from the data presented. The last paragraph should contain a short summary of the findings.

Acknowledgments: This area provides the author(s) an opportunity to thank persons who assisted in the research of the project. This could also include review, grants, outside funding.

References: This is a listing of any articles, books, that were used by the author(s) as a source of information presented but not developed during the project. References should be listed numerically in order of appearance in the LIB. References should include author(s), title, year, journal/book, volume/edition and first and last pages. In press, submitted for publication and personnel communications should be identified and reported as such.

Other comments:

- In case of microbiological identification on chromogenic agar/media, the authors need to understand that the LIB is published on yellow paper and colors will not be able to be distinguished. Possibly by 2006 the web programs will be able to handle some of these concerns.
- For microbiology/molecular biology related work nomenclatures, abbreviations may follow ASM guide lines. Specific instructions are easily available in www.ASM.org. This site can also provide some guidelines about tables, graphs.
- Standard abbreviations (e.g., AOAC) can also be used, but the authors should site/identify the source. Nonstandard abbreviations that do not have an identified source should be defined at first use.
- LIBs are currently not searchable on the web applications, but improvements are being addressed to include these capabilities in 2006.
- List of key words