The following is an outline for a draft structured Content of Standard Labeling. It contains basic operating information for health care professionals. It will be the draft to be used in a study that looks at the performance of this structured labeling compared with current labeling for a number of different devices. Each section is identified by title and includes the types of information we expect to be included in that section. Although this outline is intended to be used for the labeling of all types of medical devices, the labeling of some particular devices may not include all the information listed here for each section because the information may not be appropriate or available for that particular device.

NOTE: *The content of this draft outline was mapped from existing documents and discussions on a standard content of labeling including: IEC 82079, Physician's Labeling Regulation for the Center for Drug Evaluation and Research (CDER), Global Harmonization Task Force (GHTF) Study Group 1 model for labeling, Office of In Vitro Diagnostics and Radiation (OIR) regulation on standard content for labeling, Office of Device Evaluation (ODE) draft guidance for Standard content and format of device labeling, interviews with the OIR and ODE division directors in 2011, and input from special government employees through the Entrepreneurs in Residence (EIR) program. This document represents our current thinking.*

CONSIDERATIONS FOR A STANDARD CONTENT

(revised February 19, 2015)

The following items should be on the front page, followed by a Table of Contents

Brand or Proprietary Name

Common or Established Name

Date of Publication

Model Number

Version Number

Boxed Warning: When appropriate for inclusion, this is a statement providing restrictions and information required by FDA pursuant to section 520(e) of the Federal Food, Drug, and Cosmetic Act, a special control, or as otherwise ordered by FDA. (Proposed rule "Standard Definitions for Terms Used on Medical Device Labels and by Medical Device Labeling"; hereafter, in this document, called the proposed "Definitions Rule", February 2015)

TABLE OF CONTENTS: This title is centered and placed at the beginning of the page. However, this placement may not be the most appropriate to use for package insert. This section includes all standard headings, as explained below in this document, as well as major (minor) subheadings.

1.0 Indications for Use: This section includes a description of the disease or condition the device is intended to diagnose, treat, prevent, cure, or mitigate, together with a description of the patient population for which it is intended. (see the proposed "Definitions Rule", February 2015)

1.1 What the device does; purpose of the device

- single use or multiple use (may use a symbol)
- prescription or OTC use (may use a symbol)
- clinical environment, non-clinical environment, or both
- reprocessed (only if the device is reprocessed)

1.2 General population(s) on whom the device is used for assessment or treatment. Consider pregnancy, pediatric, or geriatric populations.

1.3 User qualifications (professional or lay person) and any required training or certification.

1.4 What the In Vitro Diagnostic (IVD) product measures or detects:

- target health condition being assessed
- whether it is qualitative or quantitative test
- target anatomy-cell, tissue, organ, part, or system examined (IVD specimen source, types(s) and preparation
- (IVD) specimen matrix(-ces) (what the substance is; the sample that is being tested)

2.0 Individual Patient or Environmental Selection Considerations: This section describes the factors for selecting certain individuals to have the test or procedure, or to use the device and the environmental conditions that affect the use of the device. It also describes the environmental and physiological conditions in which the device has not been studied.

3.0 Contraindications: This section specifies when and on whom the device should not be used; in certain patients or physiologic conditions or by certain users under certain circumstances because the known, or reasonably foreseeable, risk of use clearly outweighs any reasonably foreseeable benefit. (see proposed "Definitions Rule", February 2015).

4.0 General Warnings and Precautions:

Warnings: This section includes clinically significant risks or hazards that occur with either the proper use of, or misuse of the device, and any special care that needs to be taken to avoid the situation. The risk or hazard, if not avoided, could result in death, serious injury or effectiveness concerns. (see proposed "Definitions Rule", February 2015)

For IVDs, you must include the statement: "For In Vitro Diagnostic Use."

Precautions: This section includes alerts that inform the patient or user of a potentially hazardous situation which may result in minor or moderate effectiveness concerns or injury to the patient or the user, or damage to the equipment or other property and any special care that needs to be taken to avoid the situation. (see proposed "Definitions Rule", February 2015)

For IVDs you should add: specimen precautions for specimen collection and patient preparations, and known interfering substances.

Note: Warnings and precautions specific to steps in instructions for use should be placed immediately before each step.

5.0 Adverse Events: This section includes undesirable experiences or outcomes caused by or associated with the use of the device. This could include the number of people who had the experience or outcome (e.g., 1 out of 100 people have experienced…).

6.0 Device Description: This section explains what the device does and how it functions, the basic scientific concepts of the device, and the significant physical and performance characteristics of the device. It should contain a high-level description of how the device operates. If the theory of operation cannot be briefly described, within 1-2 paragraphs, without omitting information critical to the use of the device, consider referring the user to a detailed or lengthy theory of operation in the Resources section.

The following information is needed for IVD products:

- summary and explanation of test
- principles of the procedure
- specific performance characteristics e.g., accuracy, precision, sensitivity and specificity

7.0 Instructions for Use (IFU)/Operating Information: This section includes information on how to safely and effectively operate, use, or implant the device in the context of the approved or cleared indication for use of the device based on task analysis. Consider having separate IFUs for devices that can be used on different subpopulations (i.e. infants, adults, etc.).

7.1 Basic Operations of Controls and Displays

7.2 **Preparation**: This section focuses on tasks, with applicable specific warnings and precautions that precede each step. It may include screen shots of each task. Consider including such things as information specific to a population, expiration date, use with other devices, components needed but not supplied, calibration, connection, and/or any other information the user needs to know or do before in preparation for using the device. This is not a comprehensive list of what to include, but will be device specific.

7.3 **Use**: This section includes procedural steps, tasks, or inputs needed to be provided by the user to safely operate the device, with applicable specific warnings and precautions that precede each step. It may include screen shots of each task. Consider including such things as monitoring and programing.

For IVD Products:

- calculation and interpretation of results
- expected values or results
- retesting or confirmation testing

7.4 **After use**: This section includes procedural steps or tasks the user must do immediately or soon after the device has been used, with applicable specific warnings and precautions that precede each step. Consider including such things as disconnections, storing, disposal, and cleaning. This is not a comprehensive list of what to include, but will be device-specific.

7.5 Explantation or Device Removal

This section is for temporary implants (such as implantable infusion pumps, central lines). It includes procedural steps or tasks the user must do to remove the implanted device after it is done being used. Consider including such things as device disposal and post-implant needs for the patient.

This section is also for the unexpected removal of permanent implants (such as orthopedic implants, endosseous implants, breast implants, intra-ocular lenses). Provide a link to the following information:

- brief description of how to handle, preserve, or return the explanted device
- who to contact

8.0 General Care and Maintenance: This section contains only tasks and activities that a person using the device for treatment or diagnosis is expected to perform periodically (i.e. every week, month, etc.) or over the course of the life of the device when it is not in use. Care and maintenance activities requiring a service or maintenance technician would not be included here. Consider including such things as reuse, sterilizing, storing, disposal, and recycling. This is not a comprehensive list of what to include, but will be device-specific.

9.0 Alarms: This section contains all alarms, including clinical-related and equipment-related alarms. Consider arranging the alarms in the order of high to low priority alarms.

10.0 Troubleshooting: This section focuses on a device condition or problem that needs intervention by the practitioner; it does not include patient conditions. Consider including such things as user assistance, battery failure and power interruption. This is not a comprehensive list of what to include, but will be device-specific.

11.0 Patient Counseling: This section includes patient counseling information, based on best medical evidence that will provide supplemental aid to the health care provider when counseling a patient.

12.0 Glossary

12.1 symbols

12.2 definitions

12.3 acronyms and abbreviations

13.0 Resources: This section should include the following:

- Clinical Studies
- Other labeling information such as citations, detailed theory of operation, specifications, patient manuals, technical manuals and brochures

14.0 Contact and Reporting Information: This section should be on the back cover or last page.

Consider including the following:

- reporting of adverse events

- manufacturer information: name and address
- distributor name and address
- importer name and address
- supplier name and address
- phone number and help line
- fax number
- website URL
- warranty and refund

15.0 Date of Latest Revision: This section should be on the back cover or last page