

Receipt, Approval and Use of Labels and Labeling

Table 1 – Options and Requirements

| Label/Labeling                           | <u>Optional</u><br>Bleed<br>Lines | <u>Required</u><br>Revision<br>Specific<br>Barcode or<br>Alpha-<br>numeric<br>Label Code | <u>Required</u><br>Label<br>Revision<br>Number<br>System | <u>Required</u><br>Visual Verification<br>or<br>(100%)<br>Electrical/<br>Electromechanical |
|------------------------------------------|-----------------------------------|------------------------------------------------------------------------------------------|----------------------------------------------------------|--------------------------------------------------------------------------------------------|
| 1. Product Container Label (paper)       |                                   |                                                                                          |                                                          |                                                                                            |
| 1.1 Roll                                 | —                                 | X                                                                                        | X                                                        | X                                                                                          |
| 1.2 Cut                                  | X                                 | X                                                                                        | X                                                        | X <sup>1</sup>                                                                             |
| 2. Package Insert                        | X                                 | X                                                                                        | X                                                        | X                                                                                          |
| 3. Individual Folding Carton             | X                                 | X                                                                                        | X                                                        | X                                                                                          |
| 4. Unitizing Folding Carton              | X                                 | X                                                                                        | X                                                        | X                                                                                          |
| 5. Preprinted Tubes, Glass<br>Cartridges | —                                 | X                                                                                        | X                                                        | X                                                                                          |
| 6. Printed Foil                          | —                                 | X                                                                                        | X                                                        | X                                                                                          |
| 7. Shipping Container Labels             | X                                 | —                                                                                        | X                                                        | X                                                                                          |

[X = Applies]

Note:

1. Cut Labels shall be verified by, at least, one of the following methods:

- One hundred (100) percent electronic/ electromechanical verification system; or
- One hundred (100) percent visual inspection with the examination performed by one person and independently verified by a second person.