

Guidance Number: 070

Table 1 – Options and Requirements

Label/Labeling	<u>Optional</u> Bleed Lines	<u>Required</u> Revision Specific Barcode or Alpha- numeric Label Code	<u>Required</u> Label Revision Number System	<u>Required</u> Visual Verification or (100%) Electrical/ Electromechanical
1. Product Container Label (paper)				
1.1 Roll	—	X	X	X
1.2 Cut	X	X	X	X ¹
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 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.