



WHO DOES THIS APPLY TO?

- Manufacturers, importers and distributors of drug products.

KEY POINTS:

View the most recent version of the cGMPs at:

<http://www.gpo.gov/fdsys/>

- **Part 11:** no changes
- **Part 210:** no changes
- **Part 211:** one minor change to **Section 211.122:**
 - Effective Date Note: At 77 FR 16163, Mar. 20, 2012, § 211.122 was amended by revising the introductory text of paragraph (g) and by adding paragraph (g)(4). The addition of paragraph (g)(4) became effective **Apr. 19, 2012**. The revision of the introductory text of paragraph (g) became effective **Mar. 20, 2013**. For the convenience of the user, the revised text is set forth as follows:
 - § 211.122 Materials examination and usage criteria. (g) If cut labeling is used for immediate container labels, individual unit cartons, or multiunit cartons containing immediate containers that are not packaged in individual unit cartons, packaging and labeling operations shall include one of the following special control procedures: (4) Use of any automated technique, including differentiation by labeling size and shape, that physically prevents incorrect labeling from being processed by labeling and packaging equipment.

FAQ:

Is my Blue Book dated April 1, 2011 still current?

Yes, with the one minor change noted above.

Call us today at
1-877-877-5152 ext. 210
or visit
www.QualityAndCompliance.com

Quality & Compliance QuickNote – FDA cGMP Regulations Update

Date of last update: May 2013

<http://www.qualityandcompliance.com>

9-6975 Meadowvale Town
Centre Circle, Suite 410,
Mississauga, Ontario,
L5N 2V7, Canada
TOLL FREE: 1-877-877-5152
PHONE: 905-363-1182
FAX: 905-542-7981
info@qualityandcompliance.com
www.qualityandcompliance.com

