



**B&R Compliance Associates LLC**  
*Regulatory Update Bulletin*

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**Labeling Requirements for  
Medical Gases**

Page 1 of 1

If you produce gases, which bear the “USP”, or “NF” label you are a drug manufacturer. As such, the FDA expects you to comply with Current Good Manufacturing Practices which includes maintaining strict physical control over labels and procedures to ensure that labels are current and conform to specification. Current Good Manufacturing Practices (cGMP’s) relative to human drug products are found in 21 CFR, §210 and 211. Failure to comply with these requirements and the requirements of your own SOPs can result in serious consequences.

**What elements should be included in your “Labeling” procedures?**

- Your written procedures should cover receipt, storage, issuance, return of unused labels, labels destroyed, and when to apply and remove labels to/from cylinders. SOPs should also state when labels are to be issued and where maintained (e.g., state specific secured location).
- Note: Be sure to include sample “Master” labels in your SOPs.
- Typically, Batch Production Records document & reconcile labels issued, used, destroyed/returned and distributors use a separate log (e.g., “Master Label Log”) for recording total labels in inventory.
- Note: 100% verification of label application by second person is required

**What content should appear on the label?**

- Labels shall bear the actual corporate name or the name under which business is conducted; this name may be preceded or followed by the name of the division or parent company.
- The street address, city, state, and zip code of the manufacturer shall be on the label unless it is shown in the current city or telephone directory.
- The basic marking requirements are: DOT proper shipping name; Hazard class word, number and pictorial, 1 1/16 x 1 1/16 diamond; DOT (Product UN Identification Number)
- Each label shall bear the following entries: Product composition with no abbreviations; Cylinder style and size; Cylinder content (liters of gas); Top pressure at 70 degrees
- Additional information may be placed on the label as appropriate that is of value to the consumer or required by regulations: Signal word; Statement of hazard; Precautionary measures; First aid

Note: List is not inclusive, for additional information reference a document such as CGA pamphlet C-7.

**For more information on this subject, or any other medical gases compliance issue please contact Ron Ball at (317) 297-8518, or [ron.ball@brcompliance.com](mailto:ron.ball@brcompliance.com).**