the information listed in Section 5.1.3).

5.1.5 Intermediate or API containers that are transported outside of the site's control must be sealed in a manner such that, if the seal is breached or missing, the recipient will be altered to the possibility that the contents may have been altered.

5.1.6 For material with expiration or retest dates, these must be included on the label and/or certificate of analysis.

5.1.7 Packaged or labeled materials must be examined to ensure that that they have the correct label. This examination must be part of the packaging operation and documented in the production records.

5.1.8 Labeling for APIs intended for use in clinical trials should identify the material as being for investigational use. The "investigational use" label is not required for commercial API being used for clinical trials, or for investigational API stored within the own site, which is controlled through an electronic inventory system.

5.1.9 The applicable guidance given for IMP below should be applied for any pre-printed labeling used for API.

5.2 Receipt of Pre-Printed Packaging and Labeling Materials for IMP

5.2.1 There must be written procedures for the receipt, identification, quarantine, sampling, examination and/or testing and release, and handling of pre-printed packaging and labeling material.

Note: There should be written procedures for receipt of released material from another site (e.g., Operations) to ensure that the guidance in this section is covered. It is not necessary for R&D to repeat operations performed at another sister site.

5.2.2 Pre-printed packaging/labeling materials must be received with at least a material description and suppliers batch number.

5.2.3 Pre-printed packaging/labeling material must conform to established specifications.

5.2.4 Records must be maintained for the receipt, examination or testing, and disposition of the material.

5.2.5 Pre-printed packaging/labeling materials must be physically or administratively quarantined. Status-labeling of pre-printed packaging/labeling material should be clear and unambiguous and include the following:

- Batch number
- Material name and/or code
- Material status (written or encrypted)

5.3 Label Issuance and Control for IMP

