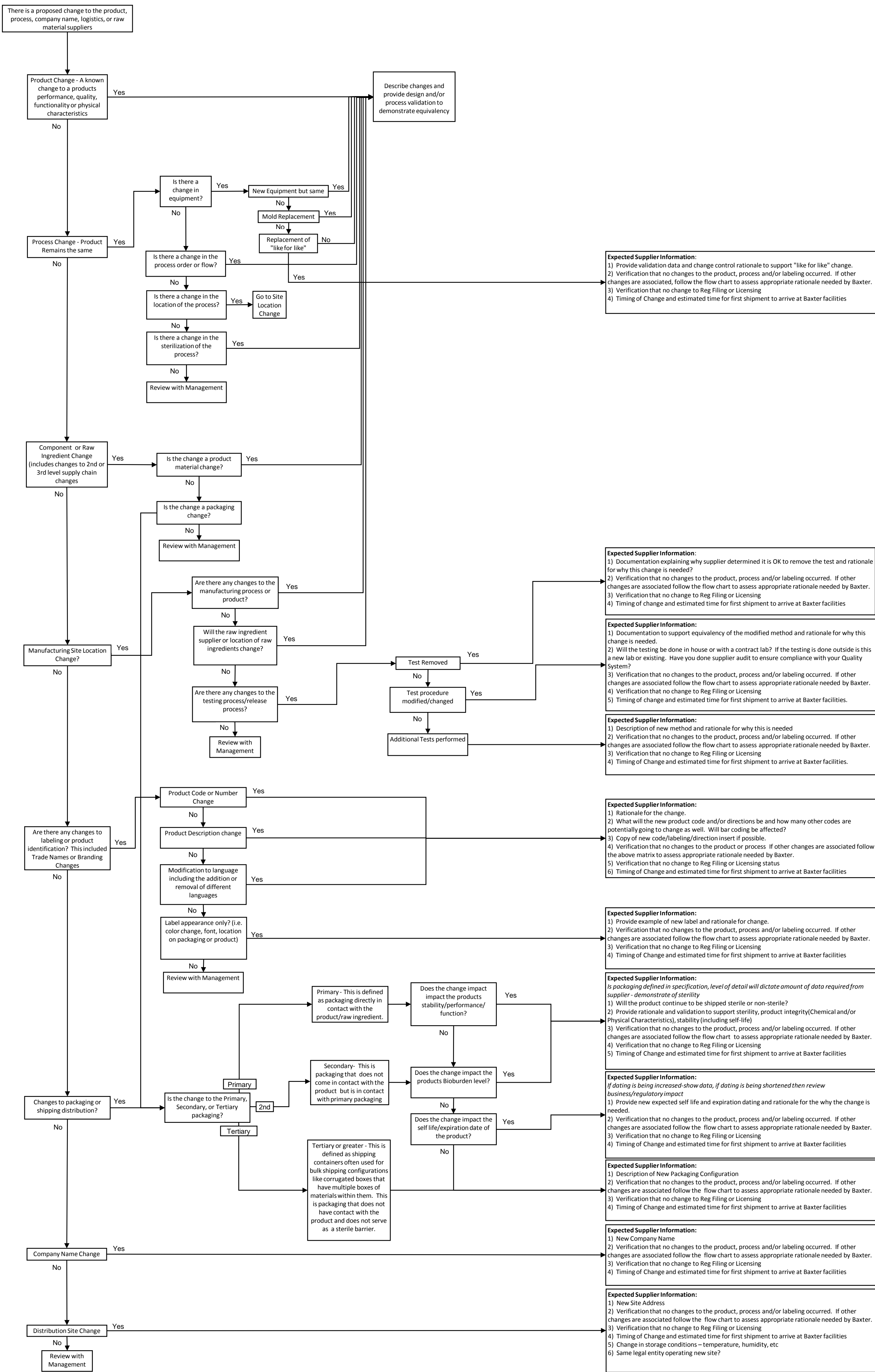


Flowchart for Identification of Expected Supplier Data for Submitted SNCs

Send all SNCs and related information to: SNC@Baxter.com



**Expected Supplier Information:**  
1) Provide validation data and change control rationale to support "like for like" change.  
2) Verification that no changes to the product, process and/or labeling occurred. If other changes are associated, follow the flow chart to assess appropriate rationale needed by Baxter.  
3) Verification that no change to Reg Filing or Licensing  
4) Timing of Change and estimated time for first shipment to arrive at Baxter facilities

**Expected Supplier Information:**  
1) Documentation explaining why supplier determined it is OK to remove the test and rationale for why this change is needed?  
2) Verification that no changes to the product, process and/or labeling occurred. If other changes are associated follow the flow chart to assess appropriate rationale needed by Baxter.  
3) Verification that no change to Reg Filing or Licensing  
4) Timing of change and estimated time for first shipment to arrive at Baxter facilities

**Expected Supplier Information:**  
1) Documentation to support equivalency of the modified method and rationale for why this change is needed.  
2) Will the testing be done in house or with a contract lab? If the testing is done outside is this a new lab or existing. Have you done supplier audit to ensure compliance with your Quality System?  
3) Verification that no changes to the product, process and/or labeling occurred. If other changes are associated follow the flow chart to assess appropriate rationale needed by Baxter.  
4) Verification that no change to Reg Filing or Licensing  
5) Timing of change and estimated time for first shipment to arrive at Baxter facilities.

**Expected Supplier Information:**  
1) Description of new method and rationale for why this is needed  
2) Verification that no changes to the product, process and/or labeling occurred. If other changes are associated follow the flow chart to assess appropriate rationale needed by Baxter.  
3) Verification that no change to Reg Filing or Licensing  
4) Timing of Change and estimated time for first shipment to arrive at Baxter facilities.

**Expected Supplier Information:**  
1) Rationale for the change  
2) What will the new product code and/or directions be and how many other codes are potentially going to change as well. Will bar coding be affected?  
3) Copy of new code/labeling/direction insert if possible.  
4) Verification that no changes to the product or process. If other changes are associated follow the above matrix to assess appropriate rationale needed by Baxter.  
5) Verification that no change to Reg Filing or Licensing status  
6) Timing of Change and estimated time for first shipment to arrive at Baxter facilities

**Expected Supplier Information:**  
1) Provide example of new label and rationale for change.  
2) Verification that no changes to the product, process and/or labeling occurred. If other changes are associated follow the flow chart to assess appropriate rationale needed by Baxter.  
3) Verification that no change to Reg Filing or Licensing  
4) Timing of Change and estimated time for first shipment to arrive at Baxter facilities

**Expected Supplier Information:**  
*Is packaging defined in specification, level of detail will dictate amount of data required from supplier - demonstrate of sterility*  
1) Will the product continue to be shipped sterile or non-sterile?  
2) Provide rationale and validation to support sterility, product integrity(Chemical and/or Physical Characteristics), stability (including self-life)  
3) Verification that no changes to the product, process and/or labeling occurred. If other changes are associated follow the flow chart to assess appropriate rationale needed by Baxter.  
4) Verification that no change to Reg Filing or Licensing  
5) Timing of Change and estimated time for first shipment to arrive at Baxter facilities

**Expected Supplier Information:**  
*If dating is being increased-show data, if dating is being shortened then review business/regulatory impact*  
1) Provide new expected self life and expiration dating and rationale for the why the change is needed.  
2) Verification that no changes to the product, process and/or labeling occurred. If other changes are associated follow the flow chart to assess appropriate rationale needed by Baxter.  
3) Verification that no change to Reg Filing or Licensing  
4) Timing of Change and estimated time for first shipment to arrive at Baxter facilities

**Expected Supplier Information:**  
1) Description of New Packaging Configuration  
2) Verification that no changes to the product, process and/or labeling occurred. If other changes are associated follow the flow chart to assess appropriate rationale needed by Baxter.  
3) Verification that no change to Reg Filing or Licensing  
4) Timing of Change and estimated time for first shipment to arrive at Baxter facilities

**Expected Supplier Information:**  
1) New Company Name  
2) Verification that no changes to the product, process and/or labeling occurred. If other changes are associated follow the flow chart to assess appropriate rationale needed by Baxter.  
3) Verification that no change to Reg Filing or Licensing  
4) Timing of Change and estimated time for first shipment to arrive at Baxter facilities

**Expected Supplier Information:**  
1) New Site Address  
2) Verification that no changes to the product, process and/or labeling occurred. If other changes are associated follow the flow chart to assess appropriate rationale needed by Baxter.  
3) Verification that no change to Reg Filing or Licensing  
4) Timing of Change and estimated time for first shipment to arrive at Baxter facilities  
5) Change in storage conditions – temperature, humidity, etc  
6) Same legal entity operating new site?