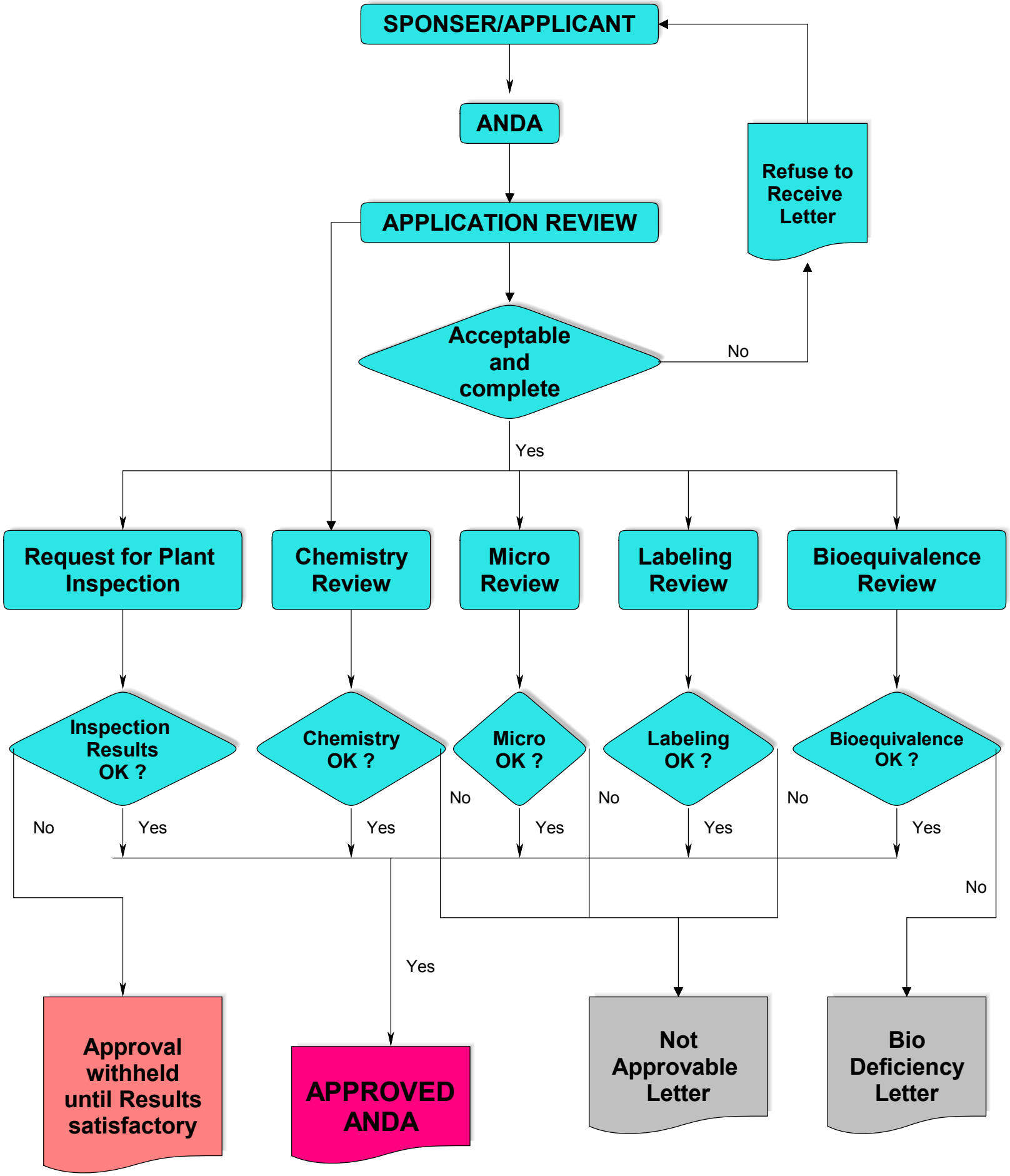
SPONSER/APPLICANT
ANDA
APPLICATION REVIEW
Refuse to Receive Letter
Acceptable and complete
No
Yes
Request for Plant Inspection
Chemistry Review
Micro Review
Labeling Review
Bioequivalence Review
Inspection Results OK ?
Chemistry OK ?
Micro OK ?
Labeling OK ?
Bioequivalence OK ?
No
Yes
Approval withheld until Results satisfactory
APPROVED ANDA
Not Approvable Letter
Bio Deficiency Letter