GENERAL INSTRUCTIONS – IDE TEMPLATE

HOW MANY COPIES DO I SEND?
• Three Copies (the original and 2 copies), make a fourth copy for your records!
• Three Hole Punched Documents
• Use at least a 1 1/2" wide left margin to allow for binding into jackets
• Submit in ACCO-like Report Covers (like the one used for this workbook)
• Preferred Colors – Original (grey), Copies (color other than grey)

Ordering Information From Corporate Express:
  Original: Gray
  Esselte: ESS12705

  Copy 1: Red
  ACCO: ACC25979

  Copy 2: Black
  ACCO: ACC25971

  Copy 3: Your choice –
  this is for your records!

WHERE DO I SEND MY IDE?

For a CDRH Submission:
  Food and Drug Administration
  Center for Devices and Radiological Health
  Document Mail Center (HFZ-401)
  9200 Corporate Blvd.
  Rockville, MD 20850
  ATTN: [Insert Appropriate Name]

For a CDER Submission:
  Food and Drug Administration
  Center for Drug Evaluation and Research
  Central Document Room
  5901-B Ammendale Road
  Beltsville, MD 20705-1266
  ATTN: [Insert Appropriate Name]

For a CBER Submission:
  Food and Drug Administration
  Center for Biologics Evaluation and Research
  HFM-99, 200N
  1401 Rockville Pike
  Rockville, MD 20852-1448
  ATTN: [Insert Appropriate Name]

WHOM DO I ADDRESS IN THE SUBMISSION?
The initial submission is usually sent to the attention of a Division Director. You can use the organization charts at the FDA website to find the right person (http://www.fda.gov/oc/orgcharts/orgchart.html). However, please just contact us and we will set you up with the correct name.
IMPORTANT NOTE:
You must state on the outer packaging (e.g. The FedEx label) of each submission what the submission contains. For example, an “IDE application”, a “supplemental IDE application” or a “correspondence concerning an IDE application”. This should also be clearly stated on your cover letter in the “RE:” section.

WHAT HAPPENS AFTER I SEND THE IDE?
- FDA will notify you in writing of the date they received an original IDE application
- That “notification letter” will contain:
  a) the IDE number that has been assigned to your application
  b) the name of the project manager that you will address your future correspondence
- FDA may
  a) approve an investigation as proposed
  b) approve it with modifications
  c) disapprove it
- An investigation may begin
  a) 30 days after FDA receives the application
  b) FDA approves an IDE for investigation

WHERE CAN I GET MORE INFORMATION?

- “Device Advice” at the FDA Website:
  o IDE Application
    http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm046706.htm
  o IDE Approval Process
    http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm046164.htm#fda_action