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?

- Regulations: 21 CFR Part 812.19 – 812.30

  http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.19
  http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.20
  http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.25
  http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.27
  http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.30

- "Device Advice" at the FDA Website:

    - IDE Application
      http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm046706.htm

    - IDE Approval Process
      http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm046164.htm#fda_action