The Division of Microbiology and Infectious Diseases (DMID) Investigational Product Label Requirements

I. Primary Container Investigational Product (IP) Label

A. Required label text:

- Statement required by 21 CFR §312.6: “Caution: New Drug-Limited by Federal (or United States) law to investigational use”
- Name/description of vaccine/drug product, including full chemical/strain name, if applicable, also may be blinded (i.e., Drug A, Drug B, Drug or Placebo)
- Lot/Control Number
- Storage conditions (temperature range)
- Concentration/dose/amount per container/volume (i.e., mg, mL, total amount; may include pre-dose amount)
- Route of administration (i.e., oral, IV, IM, IN, IH, vaginal use only)
- Manufacturing date (this is the date formulated and packaged in the primary container/closure)
- Manufactured by (whom) (city/country), with/for (whom) (city/country)

B. Recommended label text (when applicable and if space allows on the primary label):

- Single dose or multi dose
- Instructions for use/dose/administration:
  - If cannot be frozen, add “Do Not Freeze”
  - Protect from Light
  - Protect from Moisture
  - If must be shaken, add “Shake Well”
  - If cannot be shaken, add “Do Not Shake”
  - If contains thimerosal, add “contains thimerosal”
  - If contains latex, add “contains latex”.
  - For oral medications – e.g., whether they should or should not be taken with food
  - For primary containers that will be dispensed to subjects for self-administration (outside of clinic), add cautionary statement: Keep out of reach of children.

C. Exclude the following label text:

- Protocol Number
- Retest Dating (exclude for ongoing stability)

Note: Expiration Dating

If the product is on ongoing stability and the expiry date may be extended, do not include expiration date on the label, and include date of manufacture. Product manufactured in Europe must include an expiration date, even if it will be extended.

II. Secondary Container IP Packaging Label

A. Suggested label items:

- Statement required by 21 CFR §312.6: “Caution: New Drug-Limited by Federal (or United States) law to investigational use”
- Name/description of vaccine/drug product, including full chemical/strain name, if applicable, also may be blinded (i.e., Drug A, Drug B, Drug or Placebo)
- Lot/Control Number
- Storage conditions (temperature range)
- Concentration/dose/amount per container/volume (i.e., mg, mL, total amount; may include pre-dose amount, number of syringes, number doses)
- Route of administration (i.e., oral, IV, IM, IN, IH, vaginal use only)
- Manufacturing date (this is the date formulated and packaged in the primary container/closure)
- Manufactured by (whom) (city/country), with/for (whom) (city/country)
- Instructions for use/dose/administration:
  - “Do Not Freeze”
  - “Protect from Light”
  - “Protect from Moisture”
  - “Shake Well”
  - “Contains thimerosal”
  - “Contains latex”

- For oral medications – e.g., whether they should or should not be taken with food
- For primary containers that will be dispensed to subjects for self-administration (outside of clinic), add cautionary statement: “Keep out of reach of children”

B. Label items to exclude:

- Protocol Number
- Retest Dating (exclude for ongoing stability)

Note: Expiration Dating

If the product is on ongoing stability and the expiry date may be extended, do not include expiration date on the label, and include date of manufacture. Product manufactured in Europe must include an expiration date, even if it will be extended.