

# Study Products Section

Depending on your responses, additional questions may appear.

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## Study Products

**\* Study Product Type**

Indicate the type of product(s) that are required/specified to be used in this project.

- Drug
- Biologic
  - Vaccine
  - Blood and blood products
  - Cellular and gene therapy products
  - Tissue and tissue products
  - Allergenic
  - Other biologic product
    - \* Please describe.

All boxes were checked to demonstrate additional questions as applicable.

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- Food
  - Medical Food
  - Dietary Supplement
  - Food Additives
  - Infant Formula
  - Substance Generally Recognized As Safe (GRAS) for use in food
  - Other food product
    - \* Please describe.

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- Cosmetic
- Device
  - Surgical implant or prosthetic
  - Dental device
  - Electronic wearable device
  - Electronic product that emits radiation (e.g., x-ray equipment, ultrasonic therapy equipment, mercury vapor lamps, sunlamps, etc.)
  - Mobile Medical Application
  - Software or Algorithm (e.g. involving Artificial Intelligence, Machine Learning, etc.)
  - Other device
    - \* Please describe.

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- Other
  - \* Please describe.
  - The IRB will likely request more information and/or indicate which of the previous options you should select.

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### Drugs, Biologics, Foods, and Cosmetics

**\* Drug/Biologic/Food/Cosmetic Description**

Describe the Drugs/Biologics/Foods/Cosmetic products required/specified to be used in this project. Include:

- Name of product
- Purpose of its use
- For each product, if it is (1) Intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease; AND/OR (2) Intended to affect the structure or any function of the body of man or other animals.

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**\* Drugs/Biologics/Foods/Cosmetic FDA Approval Status**

Describe the FDA approval status of all Drugs/Biologics/Foods/Cosmetic products required/specified to be used in this project. For example:

- FDA Approved
- Investigational Drug requiring an IND (provide IND number and who holds IND)
- Investigational Drug that IND Exempt (be sure to explain which exemption under 21 CFR 312 it meets and how)
- Doesn't meet criteria for regulation under 21 CFR 312 (e.g., all GRAS ingredient; not used in diagnosis, cure, mitigation, treatment or prevention of disease; etc.)

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**Insurance Billing**

Will the drug or biologic be billed to the subject or their insurance carrier?

Yes

**FDA Insurance Letter**

Attach the FDA letter which approves charging for this product.

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No

**Drug/Biologic/Food/Cosmetic Documentation**

Provide documentation for all study drugs/biologics/food/cosmetic, in particular:

- Risk documentation (e.g., Investigator Brochure (IB), package insert, etc.)
- FDA Approval documentation (IND documentation, IND exemption determinations, etc.)
- Formulation/Ingredient information (for foods, supplements, etc.)

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**Devices**

**\* Device Description**

Describe the Devices required/specified to be used in this project. Include:

- Name of device
- Purpose of its use
- For each device, if it is (1) Intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease; AND/OR (2) Intended to affect the structure or any function of the body of man or other animals; BUT does not achieve its primary intended purposes through chemical action within or on the body of man or other animals, NOR is dependent upon being metabolized for the achievement of its primary intended purposes.

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**\* Device FDA Approval Status**

Describe the FDA approval status of all Devices required/specified to be used in this project. For example:

- FDA Approved
- Investigational Device requiring an IDE (provide IDE number and who holds IDE)
- Investigational Device that IDE Exempt (be sure to explain which exemption under 21 CFR §812 it meets and how)
- Doesn't meet criteria for regulation under 21 CFR §812 (e.g., study does not evaluate the device being used for safety or effectiveness; not used in diagnosis, cure, mitigation, treatment or prevention of disease; etc.)

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**\* Non-Significant Risk (NSR) Device**

Are you requesting a Non-Significant Risk determination for any Devices in this study?

Yes

**\* NSR Justification**

Provide the risk assessment and justification for any devices for which you are requesting an NSR determination. Ensure any supporting risk documentation is uploaded in the Device Documentation area below.

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No

**Device Documentation**

Provide documentation for all study devices, in particular:

- Risk documentation
- Description/Instructions (e.g., Instructions for Use (IFU), Instruction Manuals, etc.)
- FDA Approval documentation (IDE documentation, IDE exemption determinations, etc.)

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