DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

PRE-REQUEST FOR DESIGNATION (PRE-RFD) / INFORMAL SUBMISSION

FDA

The Pre-RFD / Informal submission process is available to provide informal, non-binding feedback regarding the classification of a human medical product as a drug, device, biological product, or combination product. In addition, this informal process provides information about a non-combination or combination product's assignment to the appropriate Agency Center (Center for Drug Evaluation and Research (CDER), Center for Devices and Radiological Health (CDRH), or Center for Biologics Evaluation and Research (CBER)) for premarket review and regulation.

We recommend that you complete the following form to guide you through the Pre-RFD / Informal submission process.

Contact Information for Sponsor/Applicant or Authorized Representative

Salutation	First Name	Last Name	
Position		Company Name	
Email Address *(example@email.com)*	Telephone Number *(Example +01 123-456-7890)*		Extension *(Example: 1234)*
Street Address		City/Town	
State/Province/Region		Country	Postal Code

Product Information

Sponsor/Applicant Name

Common Name *(The common name of the product)*

Trade Name *(The trade name of the product. If no trade name exists, re-enter the common name.)*

Brief Product Description *(Please provide 2 to 3 sentences describing the product.)*

Indications for Use:

Requested Classification of Product *(Optional, Select one)*

- ☐ Biologic
- ☐ Device
- ☐ Drug
- ☐ Other:
- ☐ Combination Product - Drug/Device
- ☐ Combination Product - Biologic/Device
- ☐ Combination Product - Drug/Biologic
- ☐ Combination Product - Drug/Device/Biologic
- ☐ Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P, Section 361 of PHS Act)

Designer note: This form will be made as a "508 compliant" Adobe LiveCycle PDF with entry fields after FDA (along with OMB, if applicable) gives final approval to this "layout design" version.

Designer note: Radio Buttons

Sponsor Requested Center Assignment *(Optional, Select one)*

- ☐ Center for Biologics Evaluation and Research (CBER)
- ☐ Center for Drug Evaluation and Research (CDER)
- ☐ Center for Devices and Radiological Health (CDRH)
- ☐ Other:

Designer note: Radio Buttons

PSC Publishing Services (301) 443-6740 EF

Have you previously had a submission to OCP for this product (e.g., RFD, Pre-RFD)? ☐ YES ☐ NO	If "YES," *enter previous submission number(s) (e.g., RFD, Pre-RFD; separate multiple entries with a semicolon).*
Are you updating or supplementing a pending Pre-RFD or Informal submission? ☐ YES ☐ NO	If YES, enter the Pre-RFD / Informal submission number associated with your revised Pre-RFD or responses. *(This is an eight digit number that may contain leading zeros.)*
Is there a pre-market submission *(i.e., investigational application, marketing application/submission, or any other FDA regulatory submission, e.g., a Q-submission)* for this product? ☐ YES ☐ NO	Pre-market Submission(s) *(Enter pre-market submission type and number; separate multiple entries with a semicolon)*

Submission Review Checklist

1. Contact information including your name, company's name, email address, and telephone number.
2. A complete description of the product and, if applicable, the following information.
    1. The 510(k), Premarket Approval Application (PMA), De Novo, New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Biologics License Application (BLA), or any other FDA regulatory submission number associated with the product.
    2. Name of the product and all component products; and
    3. A photo/diagram of the product
3. For products sourced from biologically-derived materials, describe how the material was processed and a characterization of the identity of the final product.
4. An explanation of how the product works. Although optional, you may include additional information describing details (i.e., study conditions/methods, identification of controls, results and conclusions) of relevant testing that supports how the product works. Please be aware that comparisons to other products or biocompatibility testing are typically not helpful in understanding how the product works.
5. An explanation of how the product will be configured and marketed. For instance, will the product have separately marketed constituent parts that are to be labeled for use together, or will it have components that either will be physically or chemically combined to make a single entity or will be co-packaged?
6. A listing of all components/ingredients, including the amount and reasoning for including each component/ingredient, in the product. If the product contains a solution/liquid/gel/powder, please provide a listing of all ingredients (active and inactive), their amount/concentration, and the reason for including each ingredient in the product.
7. Proposed use/intended use/indications for use statement.
8. Instructions for use/conditions of use.
9. All known methods of action and the mechanism(s) by which each method of action is achieved.
10. For products that might be combination products, information that you might have, if any, to support the relative contribution of different constituent parts to the overall intended therapeutic/diagnostic effects of the combination product. Although optional, you may provide a detailed description of any supporting tests/studies if such information is available and you would like FDA to consider the information.
11. A list of claims that you intend to make or have made regarding the product.

☐ I have included the above sections for this Pre-RFD / Informal submission.

Once submitted, your request cannot be edited. Please make sure you have reviewed your submission before submitting to the Office of Combination Products (OCP).