DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

REQUEST FOR DESIGNATION (RFD)

FDA

A sponsor/applicant may submit an RFD to obtain a formal agency determination of the product as a drug, device, biological product, or combination product, and/or 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, where such classification and/or Center assignment is unclear or in dispute.

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:

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.

Requested Classification of Product *(Select one)*

- ☐ Biologic
- ☐ Device
- ☐ Drug
- ☐ 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: Radio Buttons

Requested Center Assignment *(Select one)*

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

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 semi-colon)*.
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 semi-colon)*

Submission Review Checklist

1. Original RFD not exceeding 15 pages, including attachments (21 CFR 3.7(c)).
2. The identity of the sponsor, including company name and address, establishment registration number, company contact person, and telephone number (3.7(c)(1)).
3. Description of the product (3.7(c)(2)).
4. Recommended (or proposed) classification, name of the product, and all component products, if applicable (3.7(c)(2)(i)).
5. Common, generic, or usual name of the product and all component products (3.7(c)(2)(ii)).
6. Proprietary name of the product (3.7(c)(2)(iii)).
7. Identification of any component of the product that already has received premarket approval, is marketed as not being subject to premarket approval, or has received an investigational exemption. The identity of the sponsors, and the status of any discussions or agreements between the sponsors regarding the use of this product as a component of a new combination product (3.7(c)(2)(iv)).
8. Chemical, physical, or biological composition (3.7(c)(2)(v)).
9. Status and brief reports of the results of developmental work, including animal testing (3.7(c)(2)(vi)).
10. Description of the manufacturing processes, including the sources of all components (3.7(c)(2)(vii)).
11. Proposed use or indications (3.7(c)(2)(viii)).
12. Description of all known modes of action, the sponsor's identification of the single mode of action that provides the most important therapeutic action of the product, and the basis for that determination (3.7(c)(2)(ix)).
13. Schedule and duration of use (3.7(c)(2)(x)).
14. Dose and route of administration of drug or biologic (3.7(c)(2)(xi)).
15. Description of related products, including the regulatory status of those related products (3.7(c)(2)(xii)).
16. The sponsor's recommendation as to which Agency component should have primary jurisdiction based on the mode of action that provides the most important therapeutic action of the combination product. (3.7(c)(3)).
17. For combination products where the mode of action that provides the most important therapeutic action cannot be determined with reasonable certainty, the sponsor's recommendation must be based on the assignment algorithm and an assessment of the assignment of other combination products the sponsor wishes FDA to consider during the assignment of its combination product (3.7(c)(3)).

☐ I have included the above sections for this RFD 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).