Preliminary Breakthrough Therapy Designation Request (BTDR) Advice

IND #	
Sponsor	
Product	
Division	
Request Date	
Submitter Name, Phone # and Email Address	

This document will be used as a basis for the Division to comment on whether a request for a Breakthrough Therapy Designation (BTD) is appropriate, at this time, may be too preliminary, or does not currently meet the BTD criteria. If you decide to request preliminary advice, provide the information below, **summarized in 1 page or less, but not to exceed 2 pages**, and submit this officially to the IND administrative file. Please note the following:

- The Division's preliminary advice is nonbinding and will not preclude you from submitting an official BTDR in the future.
- Even if you request preliminary BTDR advice, the Division may not have enough information to determine if a BTDR is appropriate at this time. An official BTDR may be required to make this determination.
- The Division will schedule a 15 minute telecon to discuss this information.
- No written documentation of the advice provided by the Division or minutes of the telecon will be issued to the sponsor.

1. **Provide information related to whether the indication is serious and life-threatening. Briefly describe the indication and the disease for which the product is intended:**

2. **Briefly describe the drug, the drug's mechanism of action (if known), the drug's relation to existing therapy(ies):**

3. **Briefly describe available therapies, if any:**

4. **Provide information related to the preliminary clinical evidence*, including trial design, trial endpoints, treatment groups, and number of subjects enrolled:**

***For example, for Oncology/Hematology products, preliminary clinical evidence could include response rates, duration of response, and extent of prior therapies.**