CENTER FOR DRUG EVALUATION AND RESEARCH
MEDICAL NECESSITY DETERMINATION FORM

Date of Medical Necessity Determination Request:

Drug Product:

Dosage Form:

Name of Review Division Making Determination:

Name of Person(s) Making Determination:

Instructions:

Please evaluate the medical need of this product by answering the questions below. A medically necessary drug product is used to treat or prevent a serious disease or medical condition for which an acceptable alternative drug product or therapy is not available, that is judged by CDER medical staff to be an appropriate substitute or there is an inadequate supply of an acceptable alternative as determined by the Drug Shortage Staff. Alternative drug products are those that can be used to treat the same condition or disease state as that of the drug in review. In addition, keep in mind both the labeled and off label indications and uses. Alternative drug products do not equate to either the branded product or the generics that may or may not be available. Your determination should be based solely on the drug product and answers to the questions below. In conjunction with this medical necessity determination, the Drug Shortage staff will complete a market assessment. When necessary, a separate Health Hazard Evaluation (HHE) will be requested by the Office of Compliance to address newly identified defects, impurities, and/or risks associated with this drug product.

Based on the medical necessity determination by the review division and other factors, an assessment will then be made by the Drug Shortage Staff as to the most appropriate path forward to prevent or alleviate shortage.

1. What is (are) the labeled indication(s) for this drug product?

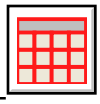
2. Is (are) there important "off-label" use(s) for this drug product?
(Please note that off-label uses can be considered medically necessary.)
[◯] No
[◯] Yes – Please explain

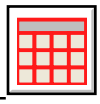
3. Is the drug product used to treat or prevent a serious disease or medical condition?
[◯] No
[◯] Yes – Please explain

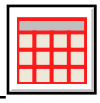
4. Is (are) there alternative drug product(s) available?
(Please note that this question refers to other drug products and not generic versions of the drug product being assessed).
[◯] No
[◯] Yes – Please explain the risk(s) and benefit(s) of the alternative product(s) as they relate to the labeled indication(s) and/or important "off-label" use(s).

5. Taking your previous responses under consideration, does your review division believe this drug product is medically necessary?
[◯] No
[◯] Yes – If only for a specific indication(s), please explain below.

6. Additional comments:

_____ 
Medical Officer Date

_____ 
Medical Officer, Team Leader Date

_____ 
Division Director Date

To enter this document into DARRTS, select "Form" under Communication Type, the appropriate Communication Application Type, "Administrative Form" under Communication Group, and "FRM-ADMIN-13-Medical Necessity Determination" under Communication Name.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