



**[RLD holder]**

Attention: **[Contact person for NDA]**

**[Contact person's position]**

**[Address]**

Dear **[Contact]**:

Re: NDA **[NDA number]**, **[brand name (nonproprietary name), dosage form, strengths]**

The Food and Drug Administration (FDA or Agency) has received a request from **[prospective generic applicant]** for assistance in obtaining supplies of **[brand name (nonproprietary name) dosage form]** for the purpose of testing a proposed generic **[nonproprietary name and dosage form]** product against **[brand name]** as the reference listed drug. We note that **[brand name]** has a Risk Evaluation and Mitigation Strategy (REMS) (including elements to assure safe use (ETASU)) that FDA has determined is necessary to ensure the benefits of this drug outweigh its risks.

**[Prospective generic applicant]** has submitted study protocols for FDA's review that FDA has determined include safety protections for testing comparable to those set forth in the FDA-mandated **[brand name]** REMS program. FDA will not consider it a violation of the REMS for **[RLD holder]** to provide to **[prospective generic applicant]** (or its agent) a quantity of **[brand name]** sufficient to allow **[prospective generic applicant]** to perform the testing necessary to support its abbreviated new drug application and otherwise meet the requirements for approval.

We note that section 505-1(f)(8) of the Federal Food, Drug, and Cosmetic Act prohibits the holder of a new drug application covered by a REMS from using any ETASU to block or delay approval of an application under section 505(b)(2) or (j) of that Act. Consistent with section 505-1(f)(8), a sufficient quantity of **[brand name]** should be supplied to **[prospective generic applicant]** to enable it to conduct the testing necessary to support its application and otherwise meet the requirements for approval. This quantity should be no less than **[insert quantity]**.

Sincerely,

**[Signature]**

cc: **[Contact at prospective generic applicant or agent that signed disclosure authorization]**