[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 are 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 precautions 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 of 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), 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 [restate quantity as requested by prospective generic applicant].

Sincerely,

[Signature]

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