

Howard Suh
Fox Rothchild LLP
101 Park Ave.
17th Floor
New York, NY 10178

May 14, 2020

Re: Docket No. FDA-2020-P-0745

Dear Mr. Suh:

This letter responds to your citizen petition dated February 11, 2020 (Petition), requesting that the Food and Drug Administration designate Ketorolac Tromethamine Tablets, 10 milligrams, abbreviated new drug application (ANDA) 074754, held by Teva Pharmaceuticals USA Inc., as a reference standard (RS) in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book).¹

As you may know, the Orange Book was updated to identify Teva Pharmaceuticals USA Inc.'s Ketorolac Tromethamine Tablets, 10 mg, ANDA 074754, as an RS. Accordingly, the Petition is dismissed as moot.

Sincerely,

Douglas C.
Throckmorton -S
Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

Digitally signed by Douglas C. Throckmorton -S
DN: cn=US, o=U.S. Government, ou=HHS, ou=FDA,
ou=People, 0.9.2342.19.200300.100.1.1=1300121270,
cni=Douglas C. Throckmorton -S
Date: 2020.05.13 16:58:12 -04'00'

¹ The Orange Book is available at <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>.