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BY ELECTRONIC SUBMISSION

Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5360 Fishers Lane. Room 1061
Rockville, Maryland 20852

RE: Withdrawal of Petition; Docket No. FDA-2020-P-2132

Dear Sir or Madam:

Petitioner has become aware of FDA's October 2020 final guidance, "Referencing Approved Drug Products in ANDA Submissions," in which FDA states that applicants may submit controlled correspondence to ask FDA to designate a new reference listed drug or select a reference standard ("RS"). Because the controlled correspondence pathway is now available to request designation of Abbreviated New Drug Application 201355 as a new RS for Nitrofurantoin Oral Suspension, 25 mg/5 mL, due to commercial unavailability of the current RS, Petitioner requests withdrawal of the above-referenced citizen petition. As such, a formal response to Docket No. FDA-2020-P-2132 is no longer necessary.

Sincerely,

Kurt R. Karst