



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

February 10, 2022

Wu Huachang, Regulatory Affairs Director
Qilu Pharmaceutical (Hainan) Co., Ltd.
No. 273-A, Nanhai Avenue, National High-Tech Zone
Haikou City, CHINA 570314

Sent via email to: huachang.wu@qilu-pharma.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug determine whether ADRUCIL (fluorouracil), 50 mg/mL, approved under New Drug Application (“NDA”) number 017959, held by PHARMACIA AND UPJOHN CO, has been voluntarily withdrawn for reasons of safety or effectiveness was received and processed under CFR 10.30 by this office on 02/10/2022.

It was assigned docket number FDA-2022-P-0152. Please refer to this docket number in future correspondence on this subject with the Agency.

Also, note that the acceptance of the petition for filing is a procedural matter and in no way reflects the agency’s decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)

cc: (lei1.yan@qilu-pharma.com)

