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

April 27, 2022

Re: Docket No. FDA-2022-P-0152

Dear Mr. Wu:

This letter responds to your citizen petition received on February 10, 2022, requesting that the Food and Drug Administration (FDA) determine whether Adrucil (fluorouracil) injection, 50 milligrams (mg)/milliliter (mL), approved under new drug application 017959, held by Pharmacia & Upjohn Co. LLC, has been voluntarily withdrawn for reasons of safety or effectiveness.

FDA has reviewed its records and determined that Adrucil (fluorouracil) injection, 50 mg/mL, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Adrucil (fluorouracil) injection, 50 mg/mL, in the "Discontinued Drug Product List" section of *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (301) 796-8363.

Sincerely,

Stacy Kane -S

Digitally signed by Stacy Kane -S
Date: 2022.04.27 15:23:31 -04'00'

Stacy Kane
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

U.S. Food & Drug Administration
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Silver Spring, MD 20993
w ww.fda.gov