



Limeng Zhou  
Yichang Humanwell Pharmaceuticals, LLC  
No. 19 Dalian Road  
Yichang Developing Zone  
Yichang, Hubei 443005  
China

October 25, 2022

Re: Docket No. FDA-2022-P-0614

Dear Petitioner:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on April 18, 2022. Your petition requests that the Agency determine whether the reference listed drug, Zyban (bupropion hydrochloride) sustained-release tablets, 150 mg approved under New Drug Application 020711 held by Glaxosmithkline, has been voluntarily withdrawn from commercial distribution or withdrawn from sale for reasons of safety or effectiveness.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

**Carol Bennett -S**

Digitally signed by Carol  
Bennett -S  
Date: 2022.10.25 15:11:29 -04'00'

Carol J. Bennett  
Deputy Director  
Office of Regulatory Policy  
Center for Drug Evaluation and Research