April 19, 2022

Limeng Zhou
Yichang Humanwell Pharmaceutical Co., Ltd
No. 19 Dalian Road
Yichang Developing Zone
Yichang, Hubei 443005
China

Sent via email to: zhoulimeng@renfu.com.cn

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug determine whether the Reference Listed Drug (RLD) ZYBAN® (bupropion hydrochloride) sustained-release tablets, 150 mg strength under New Drug Application (NDA) 020711 held by GLAXOSMITHKLINE was voluntarily withdrawn from commercial distribution or withdrawn from sale for safety or efficacy reasons was received and processed under CFR 10.30 by this office on 04/18/2022.

It was assigned docket number FDA-2022-P-0614. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, 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,

Karen P. Malvin -S
Digitally signed by Karen P. Malvin -S
Date: 2022.04.19 11:35:25 -04'00'

Karen Malvin
Acting Director
Dockets Management Staff
FDA/Office of Operations (OO)