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December 21, 2022

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

Dear Petitioner:

This letter responds to your citizen petition received on April 18, 2022, requesting that the Food and Drug Administration (FDA) determine whether ZYBAN (bupropion hydrochloride) sustained-release tablets, 150 mg strength approved under New Drug Application (NDA) 020711 held by GlaxoSmithKline LLC, has been voluntarily withdrawn from commercial distribution or withdrawn from sale for reasons of safety or effectiveness.

FDA has reviewed its records and determined that ZYBAN (Bupropion Hydrochloride) Tablets, Extended Release, 150 Milligrams, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain ZYBAN (Bupropion Hydrochloride) Tablets, Extended Release, 150 Milligrams, 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 (240) 402-0374.

Sincerely,

Michelle T. Weiner -S
Digitally signed by Michelle T. Weiner -S
Date: 2022.12.21 10:10:21 -05'00'

Michelle Weiner
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure