United States of America
FEDERAL TRADE COMMISSION
Washington, D.C. 20580

Division of Advertising Practices

February 24, 2022

Via Electronic Mail (lbrett@bbbnp.org)
Laura Brett, Esq.
Vice President
National Advertising Division
112 Madison Avenue, 3rd Floor
New York, NY 10016

Re: Advertising by PLx Pharma Inc. for Vazalore aspirin product

Dear Ms. Brett:

Thank you for your November 30, 2021 letter referring an NAD Decision involving advertising claims by PLx Pharma Inc. ("PLx") for its Vazalore aspirin product, a liquid-filled immediate release aspirin that bypasses the stomach and is sold in various doses. The NAD proceedings first began with a March 2020 NAD Challenge filed by a competitor, Bayer Healthcare LLC ("Bayer"). Although the procedural history is fairly complex, the core claims at issue are PLx's representations that Vazalore confers (1) superior gastrointestinal safety than uncoated aspirin and (2) superior absorption and antiplatelet activity than enteric-coated aspirin. These claims appeared on PLx's Vazalore website and in a television commercial.[1] In November 2021, NAD issued a Compliance Decision recommending that PLx modify its television and online advertising to clearly convey the limitations of the clinical studies underlying its claims. In its Advertiser's Statement, PLx stated it would not comply with NAD's recommendations. Accordingly, NAD referred this matter to the FTC.[2]

[1] The advertiser's "pin ball" commercial, which first aired after the initial NAD Challenge was filed, became the subject of a September 2021 Fast-Track SWIFT Challenge also filed by Bayer. In December 2021, NAD issued its Decision recommending that PLx modify the commercial to explicate the limited duration of the clinical study referenced, and NARB affirmed on appeal.

[2] After FTC had already started reviewing NAD's referral, PLx's counsel notified NAD in writing that PLx had decided to accept NAD's recommendations set forth in its Compliance Decision. Letter from Andrew B. Lustigman to Laura Brett and Annie Ugurlayan re: PLx Pharma Inc. (Jan. 27, 2022).

After reviewing the NAD case record, we had discussions with PLx's counsel regarding the claims at issue. Subsequently, PLx agreed to make significant modifications to the television and online advertising at issue, including revising its television ad and adding more prominent disclosures regarding the limited population and duration of the clinical studies on which it relies on its website. Accordingly, we have determined not to take additional action at this time. In coming to this conclusion, we considered a number of factors related to resource allocation and enforcement priorities, as well as the nature of any FTC Act violation and the type and severity of any consumer injury.

The Commission reserves the right to take such further action as the public interest may require. We appreciate your referral and the opportunity to support the NAD's self-regulatory process.

Very truly yours,

s/ Carolyn L. Hann

Carolyn L. Hann
Chief of Staff for Advertising Practices

cc: Andrew B. Lustigman, Olshan Frome Wolosky LLP