DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021695/S-016

SUPPLEMENT APPROVAL

Lupin Pharmaceuticals, Inc.
US Agent for Lupin Atlantis Holdings SA
Attention: Sudhir Kaushal, Director Regulatory Affairs
111 South Calvert Street
Harborplace Tower, 24th Floor
Baltimore, MD 21202

Dear Mr. Kaushal:

Please refer to your Supplemental New Drug Application (sNDA) dated and received August 1, 2017, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Antara 30 mg, 43 mg, 90 mg and 130 mg capsules.

This "Changes Being Effected" supplemental new drug application provides for revisions to the FULL PRESCRIBING INFORMATION, Indications and Usage section of the prescribing information to correct some inconsistencies.
Specifically, the underlined text has been added and the ~~strike through~~ text has been deleted:

"1.1 Primary Hypercholesterolemia and Mixed Dyslipidemia
Antara is indicated as adjunctive therapy to diet to reduce elevated low-density lipoprotein cholesterol (LDL-C), total cholesterol (Total-C), Triglycerides (TG), and apolipoprotein B (Apo B), and to increase high-density lipoprotein cholesterol (HDL-C) in adult patients with primary ~~hyperlipidemia~~ hypercholesterolemia or mixed dyslipidemia.

1.2 Severe Hypertriglyceridemia
Antara is also indicated as adjunctive therapy to diet for treatment of adult patients with severe hypertriglyceridemia. Improving glycemic control in diabetic patients showing fasting chylomicronemia will usually reduce fasting triglycerides and eliminate chylomicronemia thereby obviating the need for pharmacologic intervention.

Markedly elevated levels of serum triglycerides (e.g. > 2,000 mg/dL) may increase the risk of developing pancreatitis. The effect of fenofibrate therapy on reducing this risk has not been adequately studied."

These revisions were made in response to our June 27, 2017, email which responded to your email request for clarification dated April 20, 2017.

APPROVAL & LABELING

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

We note that your August 1, 2017, submission includes final printed labeling (FPL) for your package insert. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Kati Johnson, Regulatory Project Manager, at (301) 796-1234.

Sincerely,

{See appended electronic signature page}

James P. Smith, MD, MS
Deputy Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURES:
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JAMES P SMITH
09/11/2017