



NDA 207533/S-021; NDA 209830/S-009

SUPPLEMENT APPROVAL

Alkermes, Inc.
Attention: Nicholas Douris
Manager, Regulatory Affairs
852 Winter Street
Waltham, MA 02451

Dear Mr. Douris:

Please refer to your supplemental New Drug Application(s) (sNDA) pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA), and all amendments, for the following products:

Supplemental Application	Product Information	Submit Date	FDA Received Date
NDA 207533/S-021	ARISTADA (aripiprazole lauroxil) Extended-release Injectable Suspension, 441 mg, 662 mg, 882 mg and 1064 mg	October 14, 2020	October 14, 2020
NDA 209830/S-009	ARISTADA INITIO (aripiprazole lauroxil) Extended-release injectable suspension, 675 mg	October 14, 2020	October 14, 2020

These “Changes Being Effected” supplemental new drug applications provide for updated package inserts and carton labels referencing Agency’s CBE-0 supplement requests and correspondences.

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

We note that your January 15, 2021, submission includes final printed labeling (FPL) for your prescribing information, and Medication Guide. 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.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the prescribing information, and Medication Guide) with the addition of any labeling changes in pending “Changes Being Effectuated” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled *SPL Standard for Content of Labeling Technical Qs and As* at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled *SPL Standard for Content of Labeling Technical Qs and As* at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in these supplemental applications, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

CARTON AND CONTAINER LABELS

We acknowledge your January 15, 2021, submission containing final printed carton and container labeling.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

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 Kimberly Hudgens, Regulatory Business Process Manager, at (240) 402 - 4884.

Sincerely,

{See appended electronic signature page}

Gurpreet Gill-Sangha, Ph.D.
Branch Chief, B3
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):

Content of Labeling
Carton and Container Labeling



Gurpreet
Gill Sangha

Digitally signed by Gurpreet Gill Sangha
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