CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

205103Orig1s000

Trade Name:	Yosprala delayed release tablets
Generic or Proper Name:	aspirin 81 mg/omeprazole 40 mg, and aspirin 325 mg/omeprazole 40 mg
Sponsor:	Aralez Pharmaceuticals R&D Inc.
Approval Date:	September 14, 2016
Indication:	Provides for the use of Yosprala delayed-release tablets (aspirin 81 mg/omeprazole 40 mg, and aspirin 325 mg/omeprazole 40 mg) for the following: • Secondary prevention of cardiovascular and cerebrovascular events in patients at risk of developing aspirin associated gastric ulcers due to age (≥ 55) or documented history of gastric ulcers. • Decreasing the risk of developing aspirin associated gastric ulcers in patients at risk for developing aspirin-associated gastric ulcers due to age (≥ 55) or documented history of gastric ulcers.

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APPLICATION NUMBER:

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APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205103

NDA APPROVAL

Aralez Pharmaceuticals R&D Inc.
Attention: Peggy Berry
Regulatory Lead
400 Alexander Park Drive
Princeton, NJ 08540-6539

Dear Ms. Berry:

Please refer to your New Drug Application (NDA) dated and received March 25, 2013, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Yosprala (aspirin 81 mg/omeprazole 40 mg, and aspirin 325 mg/omeprazole 40 mg) delayed-release tablets.

The March 14, 2016, submission constituted a complete response to our December 16, 2014 action letter.

This new drug application provides for the use of Yosprala delayed-release tablets (aspirin 81 mg/omeprazole 40 mg, and aspirin 325 mg/omeprazole 40 mg) for the following:

- Secondary prevention of cardiovascular and cerebrovascular events in patients at risk of developing aspirin associated gastric ulcers due to age (≥ 55) or documented history of gastric ulcers.

- Decreasing the risk of developing aspirin associated gastric ulcers in patients at risk for developing aspirin-associated gastric ulcers due to age (≥ 55) or documented history of gastric ulcers.

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

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 package insert, Medication Guide). Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*, available at

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.
The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the enclosed carton and immediate container labels and submitted carton and immediate container labels, except with the revisions listed above, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 205103**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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.

We are waiving the pediatric studies requirement for this application because necessary studies are impossible or highly impracticable.

POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitments:

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Sync your system to PACER to automate legal marketing.