CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

050824Orig1s000

Trade Name:	Omeprazole delayed-release capsules, 20mg, Clarithromycin tablets, 500 mg and Amoxicillin capsules, 500 mg
Generic Name:	Omeprazole delayed-release capsules, Clarithromycin tablets, and Amoxicillin capsules
Sponsor:	DAVA Pharmaceuticals, Inc.
Approval Date:	2/8/11
Indications:	The treatment of patients with *Helicobacter pylori* infection and duodenal ulcer disease (active or up to one year history) to eradicate *H. pylori*.

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APPLICATION NUMBER:

050824Orig1s000

APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-824 **NDA APPROVAL**

DAVA Pharmaceuticals, Inc.
Attention: Susan Hamet
Vice President, Regulatory Affairs
Parker Plaza
400 Kelby Street, 10th Floor
Fort Lee, NJ 07024

Dear Ms. Hamet:

Please refer to your New Drug Application (NDA) dated September 21, 2009, received September 22, 2009, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for the co-packaging of omeprazole delayed-release capsules, 20 mg, clarithromycin tablets, 500 mg and amoxicillin capsules, 500 mg.

We acknowledge receipt of your amendment dated

December 7, 2010	December 13, 2010	December 30, 2010
January 11, 2011	January 18, 2011	January 19, 2011
February 3, 2011	February 7, 2011	

Your submission dated December 7, 2010, constituted a complete response to our July 20, 2010, action letter.

This new drug application provides for the use of omeprazole delayed-release capsules, 20 mg, clarithromycin tablets, 500 mg and amoxicillin capsules, 500 mg for the treatment of patients with *Helicobacter pylori* infection and duodenal ulcer disease (active or up to one year history) to eradicate *H. pylori*. 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, which is identical to the labeling submitted on February 7, 2011.

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

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 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.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels, as submitted on February 7, 2011, 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 titled "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 50-824**." Approval of this submission by FDA is not required before the labeling is used.

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

PROPRIETARY NAME

The proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. Your submission dated January 19, 2011 included a request for proprietary name review. This submission is still under review, and you will receive a separate communication from the Division of Medication Error Prevention and Analysis (DMEPA) at the Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research regarding the acceptability of your proposed proprietary name.

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.

Partial Waiver of Pediatric Studies

We are waiving the pediatric study requirement for ages 0 to less than 2 years because the necessary studies are impossible or highly impracticable. *H. pylor*i infection and duodenal ulcer disease is exceedingly rare in patients less than 2 years and there would be too few patients to study.

Deferral of Pediatric Studies
We are deferring submission of your pediatric study for ages 2 years to less than 17 years for this application because this product is ready for approval for use in adults and the pediatric study has not been completed.

Your deferred pediatric study required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act is a required postmarketing study. The status of this postmarketing study must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act. This required study is listed below.

PMR # 965 Single arm, safety and efficacy study to evaluate the combination of omeprazole, clarithromycin and amoxicillin (OCA) for the eradication of *H. pylori* infection in patients ages 2 to less than 17 years with active or a 1-year history of duodenal ulcer disease.

Final Protocol Submission:	February 28, 2012
Study/Trial Completion:	February 28, 2018
Final Report Submission:	February 28, 2019

Submit the protocol for our review to your PIND 101174, with a cross reference letter to this NDA. Submit final reports to this NDA. All submissions related to this required pediatric postmarketing study must be clearly designated "**Required Pediatric Assessment**".

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

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 Judit Milstein, Chief Project Management Staff at (301) 796-0763.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, MD
Director
Division of Special Pathogen and Transplant Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURES: Package Insert
Carton and Container Labeling

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

/s/

RENATA ALBRECHT
02/08/2011
Approval Letter