CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

210259Orig1s000

Trade Name:	Calquence® capsule, 100 mg
Generic or Proper Name:	acalabrutinib
Sponsor:	Acerta Pharma B.V.
Approval Date:	October 31, 2017
Indication:	For the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.

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APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 210259

ACCELERATED APPROVAL

Acerta Pharma B.V.
Attention: Yasameen Qazen, PharmD
Director, Regulatory Science
2200 Bridge Parkway, Suite 101
Redwood City, CA 94065

Dear Dr. Qazen:

Please refer to your New Drug Application (NDA) dated June 13, 2017, received June 13, 2017, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Calquence® (acalabrutinib) capsule, 100 mg.

This new drug application provides for the use of Calquence® (acalabrutinib) capsule, 100 mg for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved under the provisions of accelerated approval regulations (21 CFR 314.500), effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text. Marketing of this drug product and related activities must adhere to the substance and procedures of the referenced accelerated approval regulations.

EXPIRATION DATING PERIOD

We grant a (b)(4)-month re-test period for the drug substance when stored at or below (b)(4)°C, and a 24-month drug product expiration period when stored at controlled room temperature conditions 20°C-25°C (68°F-77°F); excursions permitted to 15°C-30°C (59°F-86°F) in the commercial packaging.

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 and text for the

patient 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 carton and immediate container labels submitted on September 27, 2017, 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 — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3)*. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 210259**." Approval of this submission by FDA is not required before the labeling is used.

ADVISORY COMMITTEE

Your application for acalabrutinib was not referred to an FDA advisory committee because the application did not raise significant safety or efficacy issues in the intended population

ACCELERATED APPROVAL REQUIREMENTS

Products approved under the accelerated approval regulations, 21 CFR 314.510, require further adequate and well-controlled clinical trials to verify and describe clinical benefit. You are required to conduct such clinical trials with due diligence. If post-marketing clinical trials fail to verify clinical benefit or are not conducted with due diligence, we may, following a hearing in accordance with 21 CFR 314.530, withdraw this approval. We remind you of your post-marketing requirement specified in your submission dated October 30, 2017. This requirement, along with required completion dates, is listed below.

PMR 3291-1 Submit the complete final report and datasets demonstrating clinical efficacy and safety from a randomized, double-blind, placebo-controlled, clinical trial of Calquence in combination with standard immunochemotherapy versus immunochemotherapy alone in patients with mantle cell lymphoma.

Enrollment Completed Submission:	12/2020
Trial Completion:	10/2023
Final Report Submission:	11/2024

Submit clinical protocols to your IND 118717 for this product. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii) you should include a status summary of each requirement in your annual report to this NDA. The status summary should include expected

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