



NDA 213535/S-006

## **SUPPLEMENT APPROVAL**

Genentech, Inc.  
Attention: Katie Lee  
Regulatory Program Management  
1 DNA Way  
South San Francisco, CA 94080

Dear Ms. Lee:

Please refer to your Supplemental New Drug Application (sNDA) dated and received March 21, 2022, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for EvrySDi (risdiplam) Powder for Oral Solution.

This Prior Approval supplemental new drug application provides for changes to the USPI Section 16.2 Storage and Handling information, Patient Information "How should I store EVRYSDI" section, and Instructions for Use "How to store EVRYSDI" section to improve patient convenience where new excursion time for the constituted solution up to max. 5 days at 40°C/75% RH.

### **APPROVAL & LABELING**

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

### **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, text for the patient package insert, and instructions for use) 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>.

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(I)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, 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).

### **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 Avani Patel, Regulatory Business Process Manager, at (240) 402 - 1845.

Sincerely,

*{See appended electronic signature page}*

Gurpreet Gill-Sangha, Ph.D.  
Branch Chief, Branch 3  
Division of Post-Marketing Activities I  
Office of Lifecycle Drug Products  
Office of Pharmaceutical Quality  
Center for Drug Evaluation and Research

Enclosures:

Content of Labeling



Gurpreet  
Gill Sangha

Digitally signed by Gurpreet Gill Sangha

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