

NDA 208684/S-005
NDA 208685/S-005

**SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT**

PTC Therapeutics, Inc.
Attention: Aparna Geddam, MS
Director, Global Regulatory Affairs
100 Corporate Court
South Plainfield NJ, 07080

Dear Ms. Geddam:

Please refer to your supplemental new drug applications (sNDAs) submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA), for the following:

NDA Number/ Supplement Number	Drug Product	Submitted and Received on:
NDA 208684/S-005	Emflaza (deflazacort) tablets	February 26, 2020
NDA 208685/S-005	Emflaza (deflazacort) oral suspension	February 26, 2020

These Prior Approval sNDAs provide for changes to the Nonclinical Toxicology Section 13.1 *Carcinogenesis, Mutagenesis, Impairment of Fertility: Carcinogenesis* of the prescribing information to include results from a study titled, "an oral carcinogenicity study of deflazacort and major human metabolites in mouse," that was conducted to fulfill postmarketing requirement 3165-1.

APPROVAL & LABELING

We have completed our review of these 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 June 24, 2021, submissions include final printed labeling (FPL) for your Prescribing Information. We have not reviewed these FPL. You are responsible for assuring that the wording in this FPL 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 FDA.gov.¹ Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information), 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 *SPL Standard for Content of Labeling Technical Qs and As*.²

The SPL will be accessible from 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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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).

FULFILLMENT OF POSTMARKETING REQUIREMENT(S)/COMMITMENT(S)

We have received your submissions dated February 26, 2021, containing the final report for the following postmarketing requirement listed in the February 9, 2017, approval letter.

3165-1 An oral carcinogenicity study of deflazacort and major human metabolites in mouse.

We have reviewed your submissions and conclude that the above requirement was fulfilled.

We remind you that there are postmarketing requirements listed in the February 9, 2017, approval letter that are still open.

¹ <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

² We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

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, contact Michael Matthews, Regulatory Project Manager, via email at Michael.Matthews@fda.hhs.gov or phone at (301) 796-3047.

Sincerely,

{See appended electronic signature page}

Teresa Buracchio, MD
Deputy Director
Division of Neurology 1
Office of Neuroscience
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
 - Prescribing Information

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

TERESA J BURACCHIO
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