NDA 217700

**ACCELERATED APPROVAL**

Day One Biopharmaceuticals, Inc.
Attention: Jerald Grace, Pharm.D.
Senior Director, Regulatory Science
2000 Sierra Point Parkway, Suite 501
Brisbane, CA 94005

Dear Dr. Grace:

Please refer to your new drug application (NDA) dated August 31, 2023, received August 31, 2023, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ojemda (tovorafenib) Tablet.

This NDA provides for the use of Ojemda (tovorafenib) Tablet for treatment of patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma (LGG) harboring a BRAF fusion or rearrangement, or BRAF V600 mutation.

## APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved under accelerated approval pursuant to section 506(c) of the Federal Food, Drug, and Cosmetic Act (FDCA) and 21 CFR 314.510, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

Marketing of this drug product and related activities must adhere to the substance and procedures of the accelerated approval statutory provisions and regulations.

## 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 and text for the Patient Package Insert). 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]

[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.

The SPL will be accessible via publicly available labeling repositories.

## CARTON AND CONTAINER LABELING

We acknowledge your April 14, 2024, submission containing final printed carton and container labeling.

## DATING PERIOD

Based on the stability data submitted to date, the expiry dating period for Ojemda (tovorafenib) Tablets shall be 24 months from the date of manufacture when stored at Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F) [see USP Controlled Room Temperature].

## RARE PEDIATRIC DISEASE PRIORITY REVIEW VOUCHER

We also inform you that you have been granted a rare pediatric disease priority review voucher, as provided under section 529 of the FDCA. This priority review voucher (PRV) has been assigned a tracking number, PRV NDA 217700. All correspondences related to this voucher should refer to this tracking number.

This PRV entitles you to designate a single human drug application submitted under section 505(b)(1) of the FDCA or a single biologics license application submitted under section 351(a) of the Public Health Service Act as qualifying for a priority review. Such an application would not have to meet any other requirements for a priority review. The list below describes the sponsor responsibilities and the parameters for using and transferring a rare pediatric disease priority review voucher.

- The sponsor who redeems the PRV must notify FDA of its intent to submit an application with a PRV at least 90 days before submission of the application and must include the date the sponsor intends to submit the application. This notification should be prominently marked, “Notification of Intent to Submit an Application with a Rare Pediatric Disease Priority Review Voucher.”
- This PRV may be transferred, including by sale, by you to another sponsor of a human drug or biologic application. There is no limit on the number of times that the PRV may be transferred, but each person to whom the PRV is transferred must notify FDA of the change in ownership of the voucher not later than 30 days after the transfer. If you retain and redeem this PRV, you should refer to this letter as an official record of the voucher. If the PRV is transferred, the sponsor to whom the PRV has been transferred should include a copy of this letter (which will be posted on our Web site as are all approval letters) and proof that the PRV was transferred.

- FDA may revoke the PRV if the rare pediatric disease product for which the PRV was awarded is not marketed in the U.S. within 1 year following the date of approval.
- The sponsor of an approved rare pediatric disease product application who is awarded a PRV must submit a report to FDA no later than 5 years after approval that addresses, for each of the first 4 post-approval years:
  - the estimated population in the U.S. suffering from the rare pediatric disease for which the product was approved (both the entire population and the population aged 0 through 18 years),
  - the estimated demand in the U.S. for the product, and
  - the actual amount of product distributed in the U.S.

You may also review the requirements related to this program by visiting FDA's Rare Pediatric Disease Priority Review Voucher Program web page.[3]

## ADVISORY COMMITTEE

Your application for Ojemda was not referred to an FDA advisory committee because the application did not raise significant safety or efficacy issues that were unexpected for a drug in the intended population.

## ACCELERATED APPROVAL REQUIREMENTS

Pursuant to section 506(c) of the FDCA and 21 CFR 314.510 you are required to conduct further adequate and well-controlled clinical trial(s) intended to verify and describe clinical benefit. You are required to conduct such clinical trial(s) with due diligence. If required postmarketing clinical trial(s) fail to verify clinical benefit or are not conducted with due diligence, including with respect to the conditions set forth below, we may withdraw this approval. We remind you of your postmarketing requirement specified in your submission dated April 18, 2024. This requirement is listed below.

4608-1 Conduct a multiregional, randomized clinical trial comparing tovorafenib to physician's choice of chemotherapy in pediatric patients with low grade glioma with RAF fusions or rearrangements, or V600 mutations, intended to verify and describe the clinical benefit of tovorafenib through assessment of overall response rate (ORR) as a primary endpoint and progression-free survival (PFS) and duration of response, as determined by blinded independent central review, as key secondary endpoints. Include the protocol-specified ORR and interim PFS analyses in the interim report.

[3] https://www.fda.gov/industry/developing-products-rare-diseases-conditions/rare-pediatric-disease-rpd-designation-and-voucher-programs

The timetable you submitted on April 18, 2024, states that you will conduct this trial according to the following schedule:

| | |
|---|---|
| Interim Report Submission: | 04/2028 |
| Trial Completion: | 10/2031 |
| Final Report Submission: | 04/2032 |

Submit clinical protocols to your IND 108340 for this product. FDA considers the term *final* to mean that the applicant has submitted a protocol, the FDA review team has sent comments to the applicant, and the protocol has been revised as needed to meet the goal of the study or clinical trial.

You must submit status reports of the progress of each clinical trial required under section 506(c) (listed above) to the NDA 180 days after the date of approval of this NDA and approximately every 180 days thereafter (see section 506B(a)(2) of the FDCA) (hereinafter "180-day reports").

You are required to submit two 180-day reports per year for each open study or clinical trial required under section 506(c). The initial report will be a standalone submission and the subsequent report will be combined with your application's annual status report (ASR) required under section 506B(a)(1) of the FDCA and 21 CFR 314.81(b)(2). The standalone 180-day report will be due 180 days after the date of approval (with a 60-day grace period). Submit the subsequent 180-day report with your application's ASR. Submit both of these 180-day reports each year until the final report for the corresponding study or clinical trial is submitted[4].

Your 180-day reports must include the information listed in 21 CFR 314.81(b)(2)(vii)(a). FDA recommends that you use FORM FDA 3989, *PMR/PMC Annual Status Report for Drugs and Biologics,* to submit your 180-day reports.[5]

180-day reports must be clearly designated "**NDA 217700 180-Day AA PMR Progress Report**."

FDA will consider the submission of your application's ASR under section 506B(a)(1) and 21 CFR 314.81(b)(2), in addition to the submission of reports 180 days after the date of approval each year (subject to a 60-day grace period), to satisfy the periodic reporting requirement under section 506B(a)(2).

[4] You are required to submit information related to your confirmatory trial as part of your annual reporting requirement under section 506B(a)(1) until the FDA notifies you, in writing, that the Agency concurs that the study requirement has been fulfilled or that the study either is no longer feasible or would no longer provide useful information.
[5] FORM FDA 3989, along with instructions for completing this form, is available on the FDA Forms web page at https://www.fda.gov/about-fda/reports-manuals-forms/forms.

Submit final reports to this NDA as a supplemental application. For administrative purposes, the cover page of all submissions relating to this postmarketing requirement must be clearly designated "**Subpart H Postmarketing Requirement(s)**."

## POSTMARKETING REQUIREMENTS UNDER 505(o)

Section 505(o)(3) of the FDCA authorizes FDA to require holders of approved drug and biological product applications to conduct postmarketing studies and clinical trials for certain purposes, if FDA makes certain findings required by the statute.

We have determined that an analysis of spontaneous postmarketing adverse events reported under subsection 505(k)(1) of the FDCA will not be sufficient to identify unexpected serious risks of carcinogenicity.

Furthermore, the active postmarket risk identification and analysis system as available under section 505(k)(3) of the FDCA will not be sufficient to assess these serious risk(s).

Therefore, based on appropriate scientific data, FDA has determined that you are required to conduct the following studies:

4608-2 Conduct a carcinogenicity study in mice to evaluate the potential serious risk of carcinogenicity.

The timetable you submitted on April 18, 2024, states that you will conduct this study according to the following schedule:

| | |
|---|---|
| Study Completion: | 03/2025 |
| Final Report Submission: | 08/2025 |

4608-3 Conduct a carcinogenicity study in rats to evaluate the potential serious risk of carcinogenicity. Submit a carcinogenicity protocol for a Special Protocol Assessment (SPA) prior to initiating the study.

The timetable you submitted on April 18, 2024, states that you will conduct this study according to the following schedule:

| | |
|---|---|
| Final Protocol Submission: | 09/2024 |
| Study Completion: | 12/2027 |
| Final Report Submission: | 05/2028 |

FDA considers the term *final* to mean that the applicant has submitted a protocol, the FDA review team has sent comments to the applicant, and the protocol has been revised as needed to meet the goal of the study or clinical trial.[6]

Finally, we have determined that only a clinical trial (rather than a nonclinical or observational study) will be sufficient to assess a known serious risk of long-term adverse effects on the growth and development of pediatric patients, and to assess a signal of a serious risk of gonadal toxicity in adolescent and young adult patients, and to identify the unexpected serious risks of drug toxicity from concomitant use with strong and moderate CYP2C8 inhibitors; drug toxicity when tovorafenib is used concomitantly with sensitive substrates of CYP3A4, CYP2C8, CYP1A2, CYP2B6, CYP2C9, and CYP2C19; and increased serious adverse reactions when tovorafenib is used concomitantly with BCRP substrates.

Therefore, based on appropriate scientific data, FDA has determined that you are required to conduct the following trials:

4608-4 Conduct comprehensive safety analyses from clinical studies that further characterize the known serious risk of long-term adverse effects of tovorafenib on growth and development, including but not limited to growth plate abnormalities, in a sufficient number of pediatric patients. Monitor patients for growth and development using age-appropriate screening tools. Include evaluations of growth as measured by height, weight, height velocity and height standard deviation scores, age at adrenarche if applicable, age at menarche if applicable (females) and Tanner stage. Monitor patients until discontinuation of study treatment or a minimum of 5 years from start of treatment, whichever occurs first. Include, in the interim report, a comprehensive safety analysis after all patients have been monitored for a minimum of 12 months from the start of study treatment.

The timetable you submitted on April 18, 2024, states that you will conduct this trial according to the following schedule:

| | |
|---|---|
| Interim Report Submission: | 04/2028 |
| Trial Completion: | 10/2031 |
| Final Report Submission: | 04/2032 |

4608-5 Conduct comprehensive safety analyses from clinical studies that further characterize the potential serious risk of gonadal toxicity in a sufficient number of adolescent and young adult patients treated with tovorafenib. Include evaluations of pubertal development and hormonal evaluation in appropriate patients. Monitor patients for a minimum of 5 years from start

[6] See the guidance for Industry *Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act (October 2019).* https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

of treatment. Post-treatment follow-up assessments including reproductive hormone measurements should be obtained at regularly scheduled intervals and after treatment cessation to assess time to gonadal function recovery. Include, in the interim report, a comprehensive safety analysis characterizing gonadal toxicity after all patients have been monitored for a minimum of 12 months from the start of study treatment.

The timetable you submitted on April 18, 2024, states that you will conduct this trial according to the following schedule:

| | |
|---|---|
| Draft Protocol (Analysis Plan) Submission: | 12/2024 |
| Final Protocol (Analysis Plan) Submission: | 04/2025 |
| Interim Report Submission: | 04/2028 |
| Trial Completion: | 10/2031 |
| Final Report Submission: | 04/2032 |

4608-6 Conduct a clinical pharmacokinetic trial of tovorafenib with a strong CYP2C8 inhibitor to evaluate the potential increased drug toxicity and provide dosage recommendations for tovorafenib when used concomitantly with strong and moderate CYP2C8 inhibitors. Design and conduct the trial in accordance with the FDA Guidance for Industry titled "Clinical Drug Interaction Studies —Cytochrome P450 Enzyme- and Transporter-Mediated Drug Interactions."

The timetable you submitted on April 18, 2024, states that you will conduct this trial according to the following schedule:

| | |
|---|---|
| Draft Protocol Submission: | 12/2024 |
| Final Protocol Submission: | 05/2025 |
| Trial Completion: | 11/2025 |
| Final Report Submission: | 04/2026 |

4608-7 Conduct a clinical pharmacokinetic trial of multi-dose tovorafenib on sensitive substrates of CYP3A4, CYP2C8, CYP1A2, CYP2B6, CYP2C9, and CYP2C19 to evaluate the potential for increased toxicity or reduced efficacy of these substrate drugs and provide appropriate drug interaction management strategies for tovorafenib when used concomitantly with these substrates. Design and conduct the trial in accordance with the FDA Guidance for Industry titled "Clinical Drug Interaction Studies — Cytochrome P450 Enzyme- and Transporter-Mediated Drug Interactions."

The timetable you submitted on April 18, 2024, states that you will conduct this trial according to the following schedule:

| | |
|---|---|
| Draft Protocol Submission: | 12/2024 |

| | |
|---|---|
| Final Protocol Submission: | 06/2025 |
| Trial Completion: | 06/2026 |
| Final Report Submission: | 12/2026 |

4608-8 Conduct a clinical pharmacokinetic trial of multi-dose tovorafenib on substrates of BCRP to evaluate the potential for increased toxicity of BCRP substrates and provide appropriate drug interaction management strategies for tovorafenib when used concomitantly with BCRP substrates. Design and conduct the trial in accordance with the FDA Guidance for Industry titled "Clinical Drug Interaction Studies —Cytochrome P450 Enzyme- and Transporter-Mediated Drug Interactions."

The timetable you submitted on April 18, 2024, states that you will conduct this trial according to the following schedule:

| | |
|---|---|
| Draft Protocol Submission: | 12/2024 |
| Final Protocol Submission: | 06/2025 |
| Trial Completion: | 06/2026 |
| Final Report Submission: | 12/2026 |

FDA considers the term *final* to mean that the applicant has submitted a protocol, the FDA review team has sent comments to the applicant, and the protocol has been revised as needed to meet the goal of the study or clinical trial.[7]

Submit clinical protocol(s) to your IND 108340 with a cross-reference letter to this NDA. Submit nonclinical and chemistry, manufacturing, and controls protocols and all final report(s) to your NDA. Prominently identify the submission with the following wording in bold capital letters at the top of the first page of the submission, as appropriate: **Required Postmarketing Protocol Under 505(o), Required Postmarketing Final Report Under 505(o), Required Postmarketing Correspondence Under 505(o).**

Section 505(o)(3)(E)(ii) of the FDCA requires you to report periodically on the status of any study or clinical trial required under this section. This section also requires you to periodically report to FDA on the status of any study or clinical trial otherwise undertaken to investigate a safety issue. Section 506B(a)(1) of the FDCA, as well as 21 CFR 314.81(b)(2)(vii) requires you to report annually on the status of any postmarketing commitments or required studies or clinical trials.

FDA will consider the submission of your annual report under section 506B(a)(1) and 21 CFR 314.81(b)(2)(vii) to satisfy the periodic reporting requirement under section 505(o)(3)(E)(ii) provided that you include the elements listed in 505(o) and 21 CFR 314.81(b)(2)(vii). We remind you that to comply with 505(o), your annual report

[7] See the guidance for Industry *Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act (October 2019).* https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

must also include a report on the status of any study or clinical trial otherwise undertaken to investigate a safety issue. Failure to submit an annual report for studies or clinical trials required under 505(o) on the date required will be considered a violation of FDCA section 505(o)(3)(E)(ii) and could result in enforcement action.

**POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B**

We remind you of your postmarketing commitments:

4608-9 Complete the FIREFLY-1 trial, including your planned additional follow-up for the 137 patients with relapsed or refractory low-grade glioma harboring a BRAF alteration enrolled to Arms 1 and 2 of FIREFLY-1 and treated with tovorafenib, to further characterize the overall response rate (ORR) and duration of response (DoR) as per Response Assessment in Pediatric Neuro-oncology (RAPNO) criteria including assessment by an independent review committee (IRC) for patients enrolled to Arm 1. Include, in the interim report, an analysis of ORR and DoR in Arm 1 as per RAPNO criteria including assessment by an IRC after all Arm 1 patients have completed a minimum of 26 cycles of treatment in the FIREFLY-1 trial.

The timetable you submitted on April 18, 2024, states that you will conduct this study according to the following schedule:

| | |
|---|---|
| Interim Report Submission: | 03/2025 |
| Trial Completion: | 05/2027 |
| Final Report Submission: | 12/2027 |

4608-10 Conduct a clinical pharmacokinetic trial with a strong or moderate CYP2C8 inducer with tovorafenib to evaluate the effect of a strong or moderate CYP2C8 inducer on decreasing the systemic exposure of tovorafenib and provide dosage recommendations for tovorafenib when used concomitantly with CYP2C8 inducers. Design and conduct the trial in accordance with the FDA Guidance for Industry titled “Clinical Drug Interaction Studies —Cytochrome P450 Enzyme- and Transporter-Mediated Drug Interactions.”

The timetable you submitted on April 18, 2024, states that you will conduct this study according to the following schedule:

| | |
|---|---|
| Draft Protocol Submission: | 12/2024 |
| Final Protocol Submission: | 05/2025 |
| Trial Completion: | 11/2025 |
| Final Report Submission: | 04/2026 |

4608-11 Conduct an appropriate analytical and clinical validation study to support the development of an in vitro diagnostic device using clinical trial data that demonstrates that the device is essential to the safe and effective use of tovorafenib for the treatment of patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma harboring a BRAF fusion or rearrangement, or BRAF V600 mutation.

The timetable you submitted on April 18, 2024, states that you will conduct this study according to the following schedule:

Final Report Submission: 07/2024

**POSTMARKETING COMMITMENTS NOT SUBJECT TO THE REPORTING REQUIREMENTS UNDER SECTION 506B**

We remind you of your postmarketing commitments:

4608-12 Submission of additional dissolution profile data using the final dissolution method (USP apparatus II, 65 rpm, 900 mL 0.1 N HCl with 0.25% SDS) for three commercial batches of Tovorafenib Tablets, 100 mg to finalize the drug product acceptance criterion for the dissolution test and support the proposed expiry date/shelf life.

Interim Report Submission: 10/23/2024
Final Report Submission: 4/23/2025

A final submitted protocol is one that the FDA has reviewed and commented upon, and you have revised as needed to meet the goal of the study or clinical trial.

Submit clinical protocols to your IND 108340 for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all postmarketing final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii) you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies/trials, number of patients/subjects entered into each study/trial. All submissions, including supplements, relating to these postmarketing commitments should be prominently labeled "**Postmarketing Commitment Protocol**," "**Postmarketing Commitment Final Report**," **or** "**Postmarketing Commitment Correspondence**."

## PROMOTIONAL MATERIALS

Under 21 CFR 314.550, you are required to submit, during the application pre-approval review period, all promotional materials, including promotional labeling and advertisements, that you intend to use in the first 120 days following marketing approval (i.e., your launch campaign). If you have not already met this requirement, you must immediately contact the Office of Prescription Drug Promotion (OPDP) at (301) 796-1200. Please ask to speak to a regulatory project manager or the appropriate reviewer to discuss this issue.

As further required by 21 CFR 314.550, submit all promotional materials that you intend to use after the 120 days following marketing approval (i.e., your post-launch materials) at least 30 days before the intended time of initial dissemination of labeling or initial publication of the advertisement. We ask that each submission include a detailed cover letter together with three copies each of the promotional materials, annotated references, and approved Prescribing Information, Medication Guide, and Patient Package Insert (as applicable).

For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs*.[8]

## METHODS VALIDATION

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

## REPORTING REQUIREMENTS

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

## REQUESTED ENHANCED PHARMACOVIGILANCE (EPV)

We request that you submit all U.S. cases that describe a wrong dose error or potential for a wrong dose error involving Ojemda, as 15-day Alert reports (as described under 21 CFR 314.80(c)(1)), for a period of 3 years following the U.S. approval date.
We request that you provide a separate narrative summary and analysis of the cases that describe a wrong dose error or potential for a wrong dose error involving Ojemda as part of your required postmarketing periodic safety report (e.g., the periodic adverse drug experience report [PADER] described under 21 CFR 314.80(c)(2)).
Your narrative summary and analysis should include an interval and cumulative assessment of each wrong dose error or the potential for a wrong dose error involving

[8] https://www.fda.gov/media/128163/download.

Ojemda, a line listing of the cases for the reporting interval, and the search terms used to identify the cases. Your narrative summary should include an assessment of the following:

- The number of cases reporting that a patient received a wrong dose or could have received a wrong dose (including close calls/near misses, intercepted errors, or circumstances capable of leading to a wrong dose error). Include a breakout of cases by the prescribed dose.
- Package size involved in the error, stage where the error originated (e.g., administration, dispensing, prescribing), setting of use (e.g., hospital, outpatient), and factors that contributed to the error (e.g., packaging design, container label or carton labeling confusion).
- Reporter recommendations or actions taken to mitigate the risk of a wrong dose error.
- Adverse events and outcomes attributed to the wrong dose error.

## POST APPROVAL FEEDBACK MEETING

New molecular entities qualify for a post approval feedback meeting. Such meetings are used to discuss the quality of the application and to evaluate the communication process during drug development and marketing application review. The purpose is to learn from successful aspects of the review process and to identify areas that could benefit from improvement. If you would like to have such a meeting with us, call the Regulatory Project Manager for this application.

## COMPENDIAL STANDARDS

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standards for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). FDA typically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise official USP monographs. More information on the USP-NF is available on USP's website[9].

[9] https://www.uspnf.com/

If you have any questions, call Opeyemi Udoka, D.P.T., Senior Regulatory Health Project Manager, at 240-402-4558 or email opeyemi.udoka@fda.hhs.gov.

Sincerely,

*{See appended electronic signature page}*

Martha Donoghue, M.D.
Acting Associate Director, Pediatric Oncology
Office of Oncologic Diseases
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert

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**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.**

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/s/

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MARTHA B DONOGHUE
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