

CERTIFICATION STATEMENT / INFORMATION (Continued)

10. If you checked box C, in number 9, provide the National Clinical Trial (NCT) Number(s) for any "applicable clinical trial(s)," for which you (the sponsor/applicant/submitter) are the "responsible party" under 42 U.S.C. § 282(j)(1)(a)(i), section 402(j)(1)(a)(i) of the Public Health Service Act referenced in the application/ submission which this Certification accompanies. (Add continuation page as necessary.)

NCT Number(s): NCT04283461 NCT04405076 NCT04470427 NCT04649151 NCT04796896

Continuation Page for #10

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.

Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. Name and Title of the Person who Signs Number 15

Name Michelle Olsen	Title Associate Director Global Regulatory Affairs
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12. Address

Address 1 (Street address, P.O. box, company name c/o) 200 Technology Square		13. Telephone and Fax Numbers (Include country code if applicable and area code) (Tel): <u>617-417-4428</u> (Fax): _____
Address 2 (Apartment, suite, unit, building, floor, etc.)		
City Cambridge	State/Province/Region MA	
Country United States	ZIP or Postal Code 02139	

14. Date of Certification

09/20/2021

15. Signature of Sponsor/Applicant/Submitter or an Authorized Representative (Sign)

Sign

Michelle Olsen

Digitally signed by Michelle Olsen
Date: 2021.09.20 18:05:51 -04'00'

This section applies only to requirements of the Paperwork Reduction Act of 1995.

*****DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*****

The burden time for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/ submission) per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

If you have additional NCT Number(s) to enter, use as many of the provided slots below as needed.

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