DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

DISCLOSURE: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

Form Approved: OMB No. 0910-0396
Expiration Date: April 30, 2009

TO BE COMPLETED BY APPLICANT

b(6)

The following information concerning [redacted], who participated
Name of clinical investigator

as a clinical investigator in the submitted study H7T-MC-TAAL (TRITON TIMI-38)
Name of clinical study, is submitted in accordance with 21 CFR part 54. The named individual has participated in financial arrangements or holds financial interests that are required to be disclosed as follows:

Please mark the applicable checkboxes.

☐ any financial arrangement entered into between the sponsor of the covered study and the clinical investigator involved in the conduct of the covered study, whereby the value of the compensation to the clinical investigator for conducting the study could be influenced by the outcome of the study;

☐ any significant payments of other sorts made on or after February 2, 1999 from the sponsor of the covered study such as a grant to fund ongoing research, compensation in the form of equipment, retainer for ongoing consultation, or honoraria;

☐ any proprietary interest in the product tested in the covered study held by the clinical investigator;

☒ any significant equity interest as defined in 21 CFR 54.2(b), held by the clinical investigator in the sponsor of the covered study.

Details of the individual's disclosable financial arrangements and interests are attached, along with a description of steps taken to minimize the potential bias of clinical study results by any of the disclosed arrangements or interests.

NAME	TITLE
William Macias, M.D.	Senior Medical Fellow II (Medical Director)
FIRM / ORGANIZATION Eli Lilly and Company	
SIGNATURE William Macias	DATE 10/12/2007

Paperwork Reduction Act Statement

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 control number. Public reporting burden for this collection of information is estimated to average 4 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to:

Department of Health and Human Services
Food and Drug Administration
5600 Fishers Lane, Room 14-72
Rockville, MD 20857

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FDA-3455 Attachment: H7T-MC-TAAL- [redacted]

Country	Investigator Number	Investigator Name	Information to Disclose	# Subjects Enrolled	% of Total Subjects
[redacted]	[redacted]	[redacted]	$25,084 in non-grant financial payments from Lilly (speaker fees, honoraria and/or consulting fees)	[redacted]	[redacted]

b(6)

The financial payments the investigator received did not influence, in any way, the outcome of the trial. H7T-MC-TAAL was a multi-center, double-blinded trial, with 13,608 randomized subjects.

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Name of clinical investigator

as a clinical investigator in the submitted study H7T-MC-TAAL (TRITON TIMI-38)
Name of

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☐ any proprietary interest in the product tested in the covered study held by the clinical investigator;

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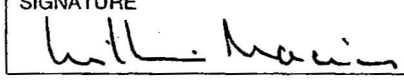
NAME	TITLE
William Macias, M.D.	Senior Medical Fellow II (Medical Director)
FIRM / ORGANIZATION Eli Lilly and Company	
SIGNATURE 	DATE 10/12/2007

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FDA-3455 Attachment: H7T-MC-TAAL- [redacted]

Country	Investigator Number	Investigator Name	Information to Disclose	# Subjects Enrolled	% of Total Subjects
[redacted]	[redacted]	[redacted]	$25,000 in honoraria payments for participation on Daiichi-Sankyo's speaker's bureau	[redacted]	[redacted]

b(6)

The financial payments the investigator received did not influence, in any way, the outcome of the trial. H7T-MC-TAAL was a multi-center, double-blinded trial, with 13,608 randomized subjects.

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With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable checkbox.

☒ (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

Clinical Investigators		
	See "FDA-3454 Attachment: H7T-MC-TAAL"	

☐ (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

☐ (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME	TITLE
William Macias, M.D.	Senior Medical Fellow II (Medical Director)
FIRM / ORGANIZATION Eli Lilly and Company	
SIGNATURE William Macias	DATE 10/12/2007

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Rockville, MD 20857

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_____ Draft Labeling (b5)

_____ Deliberative Process (b5)

X Personal Privacy (b6)

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Please mark the applicable checkbox.

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Clinical Investigators		
	See "FDA-3454 Attachment: H7T-MC-TAAH"	

☐ (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

☐ (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME	TITLE
William Macias, M.D.	Senior Medical Fellow II (Medical Director)
FIRM / ORGANIZATION Eli Lilly and Company	
SIGNATURE William L. Macias	DATE 10/12/2007

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Clinical Investigators		
	See "FDA-3454 Attachment: H7T-MC-TABL"	

☐ (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

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