FORM FDA 3674

# CERTIFICATION OF COMPLIANCE WITH REQUIREMENTS OF CLINICALTRIALS.GOV DATA BANK

## (42 U.S.C. 282(j)(5)(B))

Public Health Service Act Section 402(j) [42 USC § 282(j)] requires that clinical trials be registered at ClinicalTrials.gov, and also that a certification be submitted to the FDA stating that the requirements of Section 402(j) have been met.

## 1. APPLICATION/SUBMISSION TYPE

☐ IND (INVESTIGATIONAL NEW DRUG APPLICATION)

☐ NDA (NEW DRUG APPLICATION)

☐ BLA (BIOLOGICS LICENSE APPLICATION)

☐ EFFICACY SUPPLEMENT

☐ DEVICE 510(k)

☐ DEVICE PMA (PREMARKET APPROVAL APPLICATION)

☐ HDE (HUMANITARIAN DEVICE EXEMPTION)

## 2. APPLICABLE CLINICAL TRIALS THAT REQUIRE REGISTRATION (Mark all that apply):

☐ TRIALS OF DRUGS AND BIOLOGICS: Controlled, clinical investigation, other than a Phase I investigation, of a product subject to FDA regulation

☐ TRIALS OF DEVICES: 1) Controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and 2) Pediatric postmarket surveillance required by FDA

☐ NO APPLICABLE CLINICAL TRIALS: No clinical trials require registration under 42 U.S.C. § 282(j)

## 3. CERTIFICATION (Mark only one)

☐ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, have been met for the applicable clinical trials identified in the application. Applicable clinical trials have been registered on ClinicalTrials.gov as required.

☐ B. I certify that 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, does not apply to any clinical trial identified in the application.

☐ C. I certify that submission of this application/submission is not subject to 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act.

## 4. CLINICALTRIALS.GOV REGISTRATION INFORMATION (Complete if item 3.A is selected)

☐ All Applicable Clinical Trials provided in the table below have been registered.

|  |  |  |
| --- | --- | --- |
| NCT NUMBER | TRIAL NAME OR TITLE | TRIAL PHASE |
| {{nct\_number}} | {{trial\_title}} | {{trial\_phase}} |

## 5. CERTIFICATION STATEMENT

I certify that the statements made above are true, complete, and accurate to the best of my knowledge and that I understand that knowingly making a false statement is a criminal offense.

NAME OF CERTIFIER: {{certifier\_name}}

TITLE OF CERTIFIER: {{certifier\_title}}

ADDRESS: {{certifier\_address}}

EMAIL ADDRESS: {{certifier\_email}}

TELEPHONE NUMBER: {{certifier\_phone}}

FAX NUMBER: {{certifier\_fax}}

## SIGNATURE OF CERTIFIER:

DATE: {{signature\_date}}