**CERTIFICATION OF COMPLIANCE, UNDER 42 U.S.C. § 282(j)(5)(B), WITH REQUIREMENTS OF ClinicalTrials.gov DATA BANK**

Form FDA 3674 (9/22)

Public Law 110-85, enacted on September 27, 2007, amended the Public Health Service Act to require registration and reporting of data on certain clinical trials on the government Web site ClinicalTrials.gov.

Name of Sponsor or Applicant: {{sponsor\_name}}

**Application Type (check one):**☐ IND ☐ NDA ☐ BLA ☐ PMA ☐ HDE ☐ 510(k) ☐ de novo

Application Number (if known): {{ind\_number}}

Product Name: {{drug\_name}}

**CERTIFICATION (check one of the following boxes):**

☐ I certify that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application does not refer to a clinical trial.

☐ I certify that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application.

☐ I certify that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application and that those trials have been or will be registered as required by the statute.

NCT Numbers for Applicable Clinical Trials: {{nct\_number}}

*WARNING: A willfully and knowingly false statement is a criminal offense, U.S. Code, Title 18, Section 1001.*

SIGNATURE OF SPONSOR/APPLICANT'S AUTHORIZED REPRESENTATIVE  
  
  
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Typed Name and Title of the Certifying Official:  
  
{{certifier\_name}}, {{certifier\_title}}