Form Approved: OMB No. 0910-0120. Expiration Date: 7/31/2026. See PRA Statement below.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance

Under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. Name of Sponsor/Applicant/Submitter

2. Date of the Application/Submission

3. Address

Address 1 *(Street address, P.O. box, company name c/o)*

Address 2 *(Apartment, suite, unit, building, floor, etc.)*

City | State/Province/Region

Country | ZIP or Postal Code

4. Telephone and Fax Numbers
(Include country code if applicable and area code)

(Tel): _____

(Fax): _____

PRODUCT INFORMATION

5. **For Drugs/Biologics:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s).
For Devices: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)

Continuation Page for #5

APPLICATION / SUBMISSION INFORMATION

6. Type of Application/Submission Which This Certification Accompanies

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☐ 510(k) ☐ PDP ☐ Other

7. Include IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number *(If number previously assigned)*

If BLA was selected in item 6, provide Supplement Number

8. Serial Number Assigned to Application/Submission Which This Certification Accompanies

CERTIFICATION STATEMENT / INFORMATION

9. Check only one of the following boxes *(See instructions for additional information and explanation)*

☐ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, including 42 CFR part 11, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, including 42 CFR part 11, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that the requirements of 42 U.S.C. 282(j), including any applicable provisions of 42 CFR part 11, have been met.

Certification Statement / Information section continued on page 2

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):

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	Title

12. Address

Address 1 *(Street address, P.O. box, company name c/o)*	
Address 2 *(Apartment, suite, unit, building, floor, etc.)*	
City	State/Province/Region
Country	ZIP or Postal Code

13. Telephone and Fax Numbers *(Include country code if applicable and area code)*

(Tel): _____

(Fax): _____

14. Date of Certification

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

Sign

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
PRAStaff@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."

INSTRUCTIONS FOR COMPLETION OF FORM FDA 3674 – CERTIFICATION OF COMPLIANCE
Under 42 U.S.C. § 282(j)(5)(B), with Requirements for ClinicalTrials.gov Data Bank

Form FDA 3674 must accompany an application/submission, including certain amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. Name of Sponsor/Applicant/Submitter – This is the name of the sponsor/applicant/submitter of the drug/ biologic/device application/submission which the certification accompanies. The name must be identical to that listed on the application/submission.

2. Date – This is the date of the application/submission which the certification accompanies or should have accompanied, if submitted at a subsequent date.

3. & 4. Provide complete address, telephone number, and fax number of the sponsor/applicant/submitter.

5. Product Information – ***For Drugs/Biologics:*** Provide the established, proprietary name, and/or chemical/ biochemical/blood product/cellular/ gene therapy name(s) for the product covered by the application/ submission. Include all available names by which the product is known. ***For Devices:*** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.

Use a continuation page only if you have filled in all available spaces.

6. Type of Application/Submission – Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified (i.e. a new IND clinical protocol), check the box labeled "Other."

7. IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number – If FDA has previously assigned a number associated with the application/ submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.

8. Serial Number – In some instances a sequential serial number is assigned to the submission/application. If there is such a serial number, provide it in this field. If there is no such number, leave this field blank.

9. Certification – This section contains three different check-off boxes.

Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, including 42 CFR part 11, do not apply because no data from clinical trials are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.

Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, including 42 CFR part 11, do not apply at the time of submission of the certification to any clinical trials for which data are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.

Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply, on the date the certification is signed, to some or all of the clinical trials for which data are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies and for which the sponsor/ applicant/submitter is the "responsible party" of the applicable clinical trial included in the application/ submission. This means that, as of the date the certification is signed, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, and any provisions of 42 CFR part 11 that apply to one or more of the applicable clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies have been met by the sponsor/applicant/ submitter as the "responsible party."

10. National Clinical Trial (NCT) Numbers – If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from *www.ClinicalTrials.gov* for each applicable clinical trial for which the sponsor/applicant/submitter is the "responsible party" and for which data is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as the term "NCT" will be added automatically before number. Include any and all NCT numbers that, as of the date the certification is signed, have been assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" for which data is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies and for which the sponsor/applicant/submitter is the "responsible party." Leave this field blank if you have checked Box 9.C but, at the time the certification is completed, you have not yet received any NCT number(s) for the "applicable clinical trial(s)" for which data is included, relied upon, or otherwise referred to in the application/ submission. Use a continuation page only if you have filled in all available spaces.

11. Name and Title of Person Who Signed in number 11 – Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.

12 & 13. Provide the full address, telephone and fax numbers of the person who is identified in number 11 and signs the certification in number 15.

14. Provide the date the certification is signed. This date may be different from the date provided in number 2.

15. Signature of Sponsor/Applicant/Submitter or an Authorized Representative – The person signing the certification must sign in this field.