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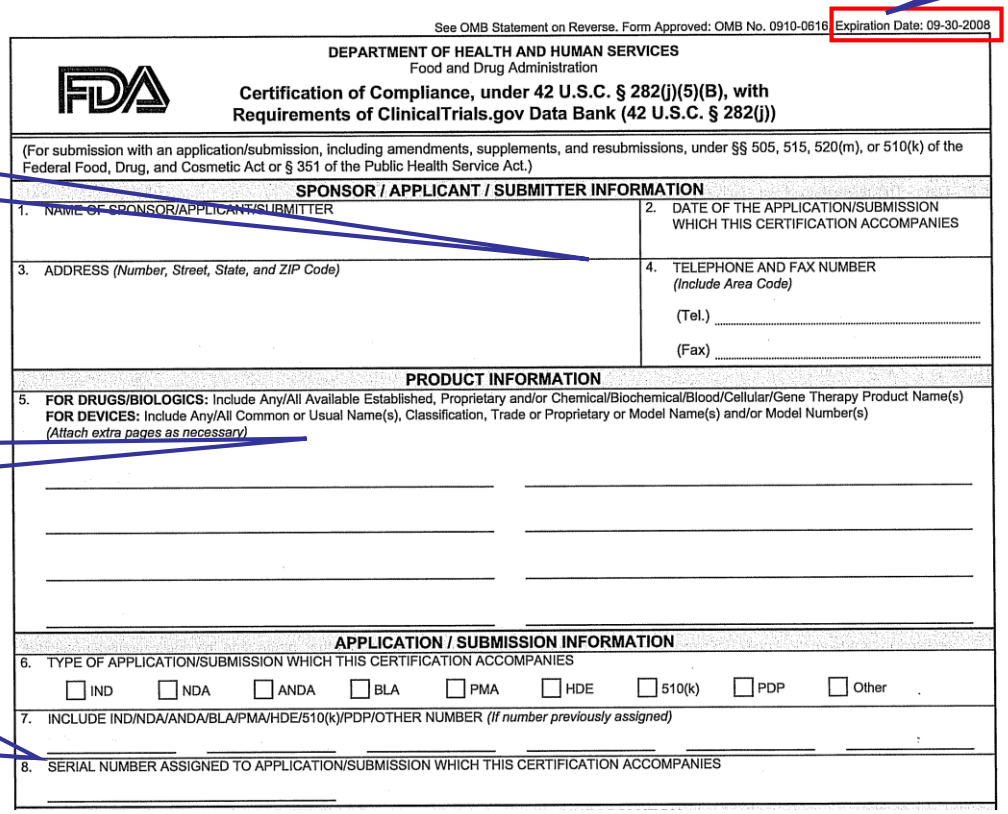
Check Date!

Boxes 1-4 should be identical to boxes 1-4 from FDA-1571

Box 5 should be the same as the list in box 5 FDA-1571

Box 7 is the IND number (if you have one). Box 8 is the same as Box 10 of FDA-1571



See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616 Expiration Date: 09-30-2008

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 (42 U.S.C. § 282(j))

(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 WHICH THIS CERTIFICATION ACCOMPANIES
3. ADDRESS *(Number, Street, State, and ZIP Code)*
4. TELEPHONE AND FAX NUMBER *(Include 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)
   (Attach extra pages as necessary)

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)*
8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

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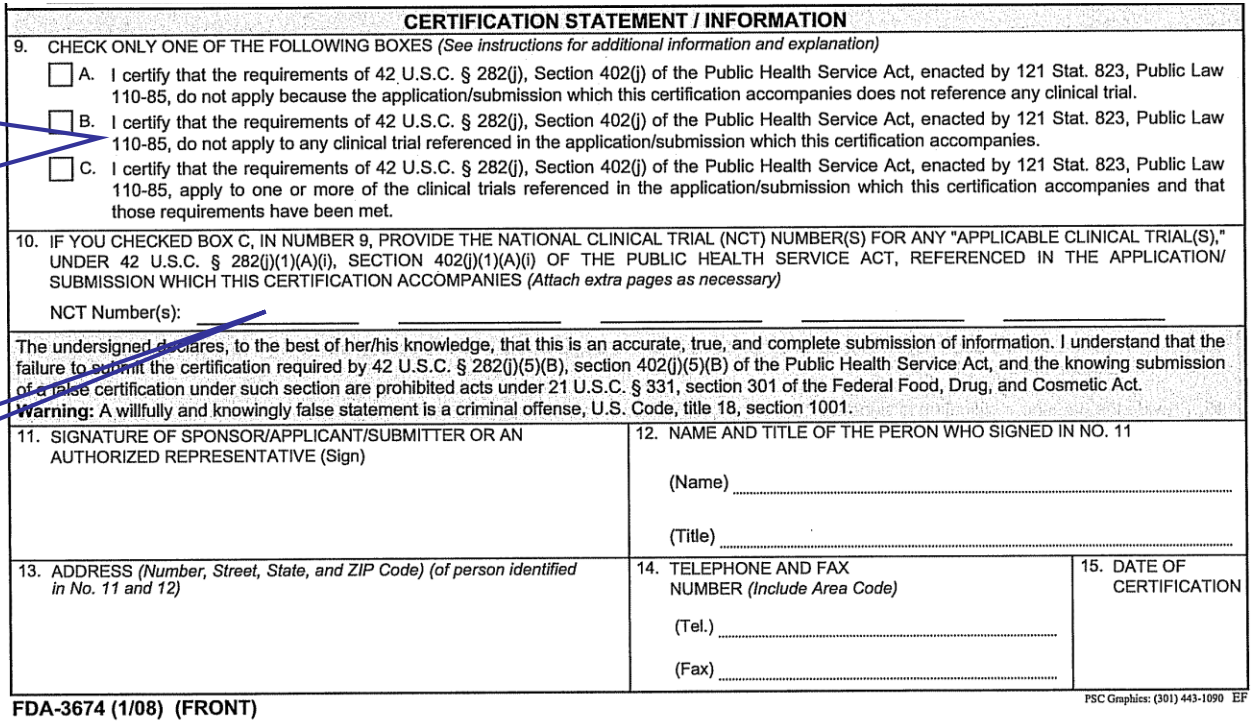
A. Studies submitted to IND are not required to be posted.
B. My study is required to be posted but I have not listed yet. I will list it in the future at appropriate time.
C. My study is posted.

List the assigned NCT number(s) if you check Box C.



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, enacted by 121 Stat. 823, Public Law 110-85, 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, enacted by 121 Stat. 823, Public Law 110-85, 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, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," 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 *(Attach extra pages as necessary)*

NCT Number(s): _____ _____ _____ _____ _____

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. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)	12. NAME AND TITLE OF THE PERON WHO SIGNED IN NO. 11 (Name) ..... (Title)	
13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in No. 11 and 12)*	14. TELEPHONE AND FAX NUMBER *(Include Area Code)* (Tel.) ..... (Fax)	15. DATE OF CERTIFICATION

FDA-3674 (1/08) (FRONT)

PSC Graphics: (301) 443-1090 EF

- Signed and dated by the Sponsor. Date in box 15 is the day the sponsor signs the form! Does not have to match the submission date listed in Box 2.
- Original goes to FDA but make a good copy for yourself!
- Required by regulation to submit with almost every submission to the IND (e.g. not IND Safety Reports).

FDA form 3674 – more details

Which Trials Must be Registered?

The trials that must be registered are called "applicable clinical trials." Under the statute, these trials generally include:

1. **Trials of Drugs and Biologics: Controlled, clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation**

   Note: ICMJE requires registration of Phase I trials with efficacy endpoints.

2. **Trials of Devices: Controlled trials with health outcomes, other than small feasibility studies, and pediatric postmarket surveillance.**

When is the Deadline for Registration?

- **In order to publish in ICJME journals, you must register prior to enrollment of the first subject.**
- **In order to comply with 42 USC § 282(j), you must register no later than 21 days after enrollment of the first subject.**

How do I Register my Study?

UNC Clinical Trials must be registered through the Office of Clinical Trials.

Please contact them by sending an email to: Barbara_Longmire@med.unc.edu From there, you will get your username and password.