

**Format Guidance, Standards Form
And Extensions
Clinical Trial Form and 510(k)**

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**Guidance for Industry and FDA Staff
Format for Traditional and
Abbreviated 510(k)s**

**Issued: August 12, 2005
(Corrected on November 17, 2005)**

**[www.fda.gov/cdrh/ode/guidance/
1567.html](http://www.fda.gov/cdrh/ode/guidance/1567.html)**

Guidance

- **The new guidance will conserve FDA and industry resources and facilitate a timely review by providing:**
 - **Specific guidance on how to format an original submission for a Traditional or Abbreviated 510(k)**
 - **Clearly defines common terms used by FDA**
 - **Recommends specific sections that should be contained in submission**
 - **Clearly defines each section recommended and provides helpful websites and additional resources to assist submitter**
 - **Recommends a format that FDA reviewers can quickly locate information contained in submission**
 - **Compliments STED**

Guidance

- The new guidance does not:
 - Describe recommendations for any specific device types
 - Recommend a format for
 - Special 510(k)s
 - 510(k) Supplements
 - PMAs
 - IDEs

What Should Be Included In Your 510(k) Submission

- **Medical Device User Fee Cover Sheet**
 - **Required for all 510(k)s**
 - **Types of submissions exempt from fee (cover sheet still required):**
 - **Third-Party Reviews**
 - **Submissions intended solely for pediatric use**
 - **A submission submitted by a state or Federal government not for commercial sale**
- **CDRH Premarket Review Submission Cover Sheet (voluntary)**

What Should Be Included In Your 510(k) Submission

- **510(k) Cover Letter**
 - Identify 510(k) holder
 - Type submission
 - Associated submissions
 - Basis for submission
- **Executive Summary**
 - concise description of the device, including the indications for use and technology;
 - device comparison table; and
 - concise summary for any performance testing in the submission.

What Should Be Included In Your 510(k) Submission

- **Indications for Use Statement**
 - Your indications for use statement should be exactly the same as the indications for use listed throughout the rest of your 510(k) submission, including the indications for use in the device labeling.
- **510(k) Summary or 510(k) Statement**
- **Truthful and Accuracy Statement**
 - This is a statement signed and dated by the submitter certifying that all information submitted in the 510(k) is truthful and accurate
- **Class III Summary and Certification**
 - If you have a Class III device, for which we have not called for PMAs, it must contain a Class III Summary and Certification

What Should Be Included In Your 510(k) Submission

- **Financial Certification or Disclosure Statement**
 - if you submit information from clinical studies, you must submit a financial certification and/or a disclosure statement for each clinical investigator who participated in your study.
- **Device Description**
 - Performance Specifications
 - Device Design Requirements
 - Identify all models, as well as all accessories or components, included in the submission

What Should Be Included In Your 510(k) Submission

- Substantial Equivalence
 - detailed comparison between device and predicate sufficient to demonstrate the substantial equivalence of the devices, as applicable, in terms of:
 - Indications for use
 - technology
 - performance specifications, including any testing
- Labeling
- Sterilization and Shelf Life
- Biocompatibility
 - Direct or indirect contact with patients, you should evaluate the biocompatibility of the patient-contacting materials.

What Should Be Included In Your 510(k) Submission

- **Software**
- **Electromagnetic Compatibility and Electrical Safety**
 - Evaluate its electromagnetic compatibility (EMC).
- **Performance Testing:**
 - Bench
 - Animal
 - Clinical

Documenting Use of Standards in 510(k) Submissions

FDA Form 3654

- **Available through Device Advice**
<http://www.fda.gov/cdrh/>
- **Available through the Standards webpage**
<http://www.fda.gov/cdrh/stdsprog.html>
- **Available through Standards Guidance documents**
<http://www.fda.gov/cdrh/guidance.html>

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

- **Purpose**

- **Provide a standardized approach to describe how a standard is adapted or applied to the subject device.**
- **Assist in streamlining the review process when standards are applied.**
- **Provide the background information needed to assess the applicability of a standard for a subject device.**

So why so much detail?

- **It all comes down to substantial equivalence:**
 - **When a standard provides options it is often because there is not one method that is appropriate for all applications so options are provided.**
 - **How did the sponsor apply the standard to the specific device under review so that the reviewer can assess whether that data supports a substantial equivalence determination.**
 - **Under what conditions was the device tested with respect to the standard.**
 - **What acceptance criteria will be used to determine that the device has achieved adequate performance.**

Summary vs. Statement

- **Has FDA changed its policy regarding a statement that a device will conform?**
 - **FDA has not changed its policy rather we are trying to clarify our policy regarding the use of standards.**
 - **The circumstances in which it is appropriate to provide a “promise” to conform to a particular standard will depend on the standard and the subject device.**
 - **The conditions and acceptance criteria need to be described a priori.**
 - **If the results do not meet the agreed upon acceptance criteria or you had to modify the device to meet conformance a new 510(k) would be necessary.**

**Certification Form:
Compliance with
Clinical Trial Databases
in FDAAA**

FDAAA §801--Expanded Clinical Trial Registry Data Bank

Expansion of clinical trials registry (ClinicalTrials.gov) to accept broader scope of trials, no longer limited to serious and life threatening diseases.

More required information for each trial

Creation of a results database

Devices now included

How Do I Register A Trial?

- **Web-based system**
 - Protocol Registration System (PRS)
 - <http://prsinfo.clinicaltrials.gov>
 - Accessible from main ClinicalTrials.gov page
- **Register through organizational accounts**
 - Currently almost 4500 org accounts
 - Manufacturers, universities, research orgs
- **Takes about 15 minutes to complete a registration form.**

Compliance

510(k) submissions must be accompanied by a certification that all applicable requirements of section 402(j) of the PHS Act have been met.

Where available, such certification must include the appropriate National Clinical Trial control numbers.

**Certification Form (Form FDA 3674):
[www.fda.gov/opacom/morechoices/
fdaforms/FDA-3674.pdf](http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf)**

Certification Form

See (OMB Statement of Executive Form Approval: OMB No. 0910-0118, Expiration Date 10-30-2008)

FDA
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 re-submissions, under §§ 505, 515, 520(a), or 510(b) 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: Indicate Any/All Analyses Established, Proprietary and/or Chemical/Biochemical/Basis of Action/Genes Therapy Product Name(s) FOR DEVICES: Indicate Any/All Classes of (List Name(s)), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s) (Attach extra pages as necessary)

6. INDICATE THE TYPE OF SUBMISSION (Check one box)
7. INDICATE THE TYPE OF APPLICATION (Check one box)
8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION

9. I HEREBY CERTIFY THAT THE INFORMATION SUBMITTED TO THE FDA IN CONNECTION WITH THIS APPLICATION/SUBMISSION IS TRUE, ACCURATE, AND COMPLETE TO THE BEST OF MY KNOWLEDGE AND BELIEF. I UNDERSTAND THAT THE FAILURE TO PROVIDE TRUE, ACCURATE, AND COMPLETE INFORMATION IN CONNECTION WITH THIS APPLICATION/SUBMISSION IS A VIOLATION OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT, AND THAT SUCH VIOLATION IS A CRIMINAL OFFENSE UNDER 21 U.S.C. § 333, SECTION 301 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT. I UNDERSTAND THAT A WILLFUL AND KNOWINGLY FALSE STATEMENT IS A CRIMINAL OFFENSE, U.S. Code, Title 18, Section 1001.

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)(5)(B), SECTION 402(j)(5)(B) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES (Attach extra pages as necessary)
NCT Number(s): _____

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)
12. NAME AND TITLE OF THE PERSON 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 (1/06) (FRONT) FD-3674 (01/06) (018)

[www.fda.gov/opacom/
morechoices/
fdaforms/FDA-3674.pdf](http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf)

Certification Form

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(i), Section 402(i) 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.

[www.fda.gov/opacom/
morechoices/
fdaforms/FDA-3674.pdf](http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf)

Certification Form

Which box should be checked?

It depends in part on whether the 510(k) includes, relies upon, or refers to an applicable clinical trial (as that is defined in 42 U.S.C. § 282(j)(1)(A))

Draft Guidance

- **Draft Guidance: Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions, April 2008**

www.fda.gov/oc/initiatives/fdaaa/guidance_certifications.html

- **Proposes that only original 510(k)s that contain clinical data (not Supplements) require the Certification Form**

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Extension Policy

- **Regulations state 30 days**
- **CDRH gives automatic 90 days**
- **Applicant may request up to 180 days from the date of the request for additional information**
- **Request must be sent to the Document Mail Center**

White Oak Consolidated Campus

- **The Center for Devices and Radiological Health will be moving to Silver Spring, Maryland**
- **Scheduled for Spring 2009**
- **Look for Federal Register announcements regarding actual dates and new mailing addresses**

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