

From: OC GCP Questions
To: [REDACTED]
Subject: RE: De novo petitions and clinicaltrials.gov - clarification requested
Date: Thursday, September 04, 2014 8:25:00 AM

Dear [REDACTED],

I apologize for the delay in responding to your question. As you are aware, Title VIII of FDAAA defines a applicable device clinical trial as a prospective clinical study of health outcomes comparing an intervention with a device subject to section 510(k), 515, or 520(m) of the Food Drug and Cosmetic Act against a control in human subjects (other than a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes).” Clinical trials which meet this definition must register with ClinicalTrials.gov, as required by the statute.

This statutory definition does not reference section 513(f)(2) of the FD&C Act. Whether the clinical trials conducted in support of a de novo submission are subject to section 510(k), and thus fall within the statutory definitions of Title VIII of FDAAA may depend on the decision made on the de novo submission.

The sponsor may wish to consult with legal counsel to evaluate whether or not such trials should be registered with ClinicalTrials.gov.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Patrick J. McNeilly, Ph.D., C.I.P.
Office of Good Clinical Practice
Food and Drug Administration

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [REDACTED]
Sent: Friday, August 22, 2014 7:44 AM
To: OC GCP Questions
Cc: [REDACTED]
Subject: De novo petitions and clinicaltrials.gov - clarification requested

Dear Ms. Foltz: Thank you for the quick response. I have a follow-up question for clarification. Below is a section from the reference you provided to ELABORATION OF DEFINITIONS OF RESPONSIBLE PARTY AND APPLICABLE CLINICAL TRIAL (March 9, 2009). The only issue relevant to my question is whether a device brought to market under a de novo petition is “subject to section 510(k)”.

(3) *A Device Subject to Section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act:* In the view of the agency, a device (including a significant risk device for which approval of an investigational device exemption (IDE) is required under section 520(g) of the FDC Act; a non-significant risk device that is considered to have an approved IDE in accordance with 21 CFR § 812.2(b); or a device that is exempt from the submission requirements of 21 CFR Part 812) is subject to section 510(k), 515, or 520(m) of the FDC Act if any of the following is required before it may be legally marketed: (1) a finding of substantial equivalence under section 510(k) permitting the device to be marketed; (2) an order under section 515 of the FDC Act approving a premarket approval application for the device; or (3) a humanitarian device exemption under section 520(m) of the FDC Act.

Therefore, my original question can be better framed by asking whether a submission to FDA via a de novo petition [as per Section 513(f)(2)] is considered to be subject 510(k). I am limiting my question to devices submitted under 513(f)(2) that would fall under Class II. De novo submissions are listed on FDA’s website under “Device classification under Section

513(a)(de novo)" <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm> rather than under "510(k) Premarket Notification" <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm> which is consistent with the notion that a submission made under a de novo petition as per Section 513(f)(2) is not "subject to section 510(k)" and therefore is not encompassed by the clinicaltrial.gov regulations.

Am I correct in this assumption? If not, please help me understand FDA's policy so that I may explain it to my client. Thank you.

[REDACTED]

From: OC GCP Questions [<mailto:gcp.questions@fda.hhs.gov>]

Sent: Thursday, August 21, 2014 1:34 PM

To: [REDACTED]

Subject: RE: De novo petitions and clinicaltrials.gov

Dear [REDACTED]:

The provisions of the statute with respect to registration and submission of results apply to applicable clinical trials conducted. If the trial is an applicable clinical trial – that is the determinant of the applicability of the statute to the trial and not whether or not it is a de novo petition. You can find the draft elaboration of definitions document on NIH's website at <http://prsrinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf> and the statute at <http://www.gpo.gov/fdsys/pkg/PLAW-110publ85/pdf/PLAW-110publ85.pdf#page=82> to determine if a clinical trial being conducted (device or drug) is an applicable clinical trial and subject to the statutory requirements.

I hope that this information is helpful. Please contact us at gcp.questions@fda.hhs.gov if you have further questions. Since many questions and concerns regarding good clinical practices have been addressed over time, some individuals may find it useful to access a set of redacted GCP inquiries found at the following web address:
<http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriesToFDAonGoodClinicalPractice/default.htm>

Sincerely,

Bridget A. Foltz, MS, MT(ASCP)

Policy Analyst, Office of Good Clinical Practice

Office of the Commissioner, Food and Drug Administration

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From: [REDACTED]

Sent: Tuesday, August 19, 2014 3:42 PM

To: OC GCP Questions

Cc: Bruce MacFarlane

Subject: De novo petitions and clinicaltrials.gov

Do the requirements of ClinicalTrials.gov apply to de novo petitions?

I know they apply to 510(k)s, but FDA's website:

<http://www.fda.gov/scienceresearch/specialtopics/runningclinicaltrials/fdasroleclinicaltrials.govinformation/default.htm#ident> does not mention de novo petitions.

If the requirements do apply to de novo petitions (under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act), please provide a rationale, as I am a regulatory affairs consultant seeking an answer for a client, and the client will demand some sort of evidence. Any help will be appreciated. Thank you.

[REDACTED]