What's New with the 1571 Form?

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What is the Form Used For?

- Cover sheet for Investigational New Drug Application (IND) submissions
- Indicates what is being provided in the submission
- Captures information tracked by FDA systems

Why Was the Form Updated?

- Need for additional tracking (e.g., rare disease information)
- Need to capture Expanded Access Use INDs and protocols, and Exception from Informed Consent Requirements
- Need to clarify types of information being submitted and provide clear and concise instructions
- Need to account for proliferation of electronic submissions

When Was the Form Updated?

- Release 1: October 1, 2012
  - 508-compliant, fillable PDF
  - Updated Instructions
  - Additional check boxes to capture the information contained in the submission
  - Continuation pages
- Release 2: February 15, 2013
  - New fields for Name, Address, and Signature of Countersigner

What Was Updated?

Field 7: (Proposed) Indication for Use

Added the following:

- Is this indication for a rare disease (prevalence <200,000 in U.S.)?
- Does this product have an FDA Orphan Designation for this indication?
  - If yes, provide the Orphan Designation number for this indication.

What Was Updated?

Field 11: Contents of Submission

Added the following:

- Development Safety Update Report (DSUR)

Protocol Amendment(s)

- PMR/PMC Protocol

Information Amendment(s)

- Statistics
- Clinical Pharmacology

What Was Updated?

Field 11: Contents of Submission

Added the following:

Request for:

- ❑ Meeting
- ❑ Proprietary Name Review
- ❑ Special Protocol Assessment
- ❑ Formal Dispute Resolution

What Was Updated?

Field 12:

Added the following:

- ❑ Emergency Research Exception From Informed Consent Requirements

Expanded Access Use, 21 CFR 312.300

- ❑ Individual Patient, Non-Emergency
- ❑ Individual Patient, Emergency
- ❑ Intermediate Size Patient Population
- ❑ Treatment IND or Protocol

What Was Updated?

Field 13: Added the following:

- Biosimilar User Fee Cover Sheet (*Form FDA 3792*)
- Clinical Trials Certification of Compliance (*Form FDA 3674*)

What Was Updated?

Fields 17 and 21:

- FAX number and Email Address of Sponsor or Sponsor's Authorized Representative

Fields 23 and 24:

- Name of Countersigner
- Address of Countersigner

Field 26:

- Signature of Countersigner

LIVE WALK-THROUGH OF Form FDA 1571 WITH MOCK DATA

FAQs – Version and Compatibility

Question: What is the most current version of the 1571 Form that should be used? Is the previous version still acceptable to use for eCTD submissions?

Answer: The most current version of the 1571 Form is posted on the FDA Forms website. Although previous versions won't be rejected, we strongly recommend that the newest version of an FDA form is used since updates were made to comply with new regulations and/or to ensure important information can be automatically and efficiently captured by FDA systems. The expiration date for the current form is April 30, 2015 and the version date in the left footer is 1/13. If an update is made, a new date would be indicated in the left footer.

FAQs – Version and Compatibility

Question: What versions of Adobe Acrobat are compatible with the 508 compliant, fillable pdf 1571 Form?

Answer: Adobe Acrobat 8 or 9 (Versions 1.7 and 1.8).

FAQs – Version and Compatibility

Question: Can we remove or modify the security settings on the 1571 Form and submit it?

Answer: The only version of the 1571 Form which should be included in submissions is the version posted on the FDA Forms website. Sponsors should complete the form, but not modify the security settings or make other changes to the form since the approved, secured, posted form has been tested, approved and allows for automated processing of submissions to CDER and CBER.

FAQs – Zip/Postal Code

Question: As certain countries outside the US only use only 4 digits for the ZIP/Postal code, is it acceptable to insert an additional space behind or before the ZIP/Postal code in order to comply with the 5-digit restriction for this field?

Answer: The zip code field is a free text field to allow foreign companies to type in code that would be relevant to their area. It does not have a 5 digit limit. The only place there is a 5 digit limit is at the counter-signer area, which is field 24. All other zip codes are free text, so letters and numbers may be entered.

FAQs – Serial Numbers

Question: For a pre-submission to an IND, should we start with serial number 0000 or 0001?

Answer: The 1571 Form is not required for pre-submissions to an IND. If the 1571 Form is included with a pre-submission to allow for automated processing and/or indicate the purpose for the submission, the serial number field should be left blank.

FAQs – Transfer of Obligations

Question: The revised 1571 Form has a continuation page for field 14 (transfer of sponsor obligations to a contract research organization), which allows this information to be added directly into the form. Should I still submit a separate transfer of obligations document in Module 1.3.1.4 of the eCTD?

Answer: Information entered for field 14 and all sections of the 1571 Form should be correct and complete for extraction purposes. Transfer of obligation information can still be provided in Module 1.3.1.4 but not instead of including the information in field 14 of the 1571 Form.

FAQs – Transfer of Obligations

Question: Should the continuation page for field 14 be included in every submission as long as the information remains applicable to the IND?

Answer: If there has been no change in the contract research organization information provided in the initial submission (or subsequent amendment), the sponsor is not required to resubmit it with each amendment to the IND, but may incorporate the information by reference (21 CFR 312.23(b)). This means you should check “yes” where appropriate and on the continuation page you should reference the submission date and sequence that contains the information.

FAQs – Signature

Question: Can a third party provider contracted solely to compile, publish, and dispatch an application via the FDA Electronic Submission Gateway (ESG) sign-off on the 1571 Form?

Answer: No. The 1571 Form must be signed by the Sponsor or Sponsor's Authorized Representative. This person takes responsibility for the application and agrees to comply with all applicable laws and regulations. A third party provider contracted *solely* to compile, publish, and dispatch an application via the FDA ESG cannot sign-off on behalf on the Sponsor prior to submission to the FDA.

FAQs – Signature

Question: It will be very difficult to have the Sponsor's Authorized Representative identified in field 17 sign-off on every submission to the IND. May a proxy electronically sign on behalf of the Sponsor's Authorized Representative in field 25, if the electronic signature block clearly states this? Our intent is that if there are questions or issues the responsible point of contact is the Sponsor's Authorized Representative listed in fields 17 and 25.

Answer: It is acceptable to have a proxy sign on behalf of the Sponsor's Authorized Representative, if the electronic signature block clearly states that the proxy is signing on behalf of the Sponsor's Authorized Representative.

Common Issues to Avoid

- Incorrect or missing information
- Incorrect or missing application number
- Information that's inconsistent with the information in the eCTD us-regional.xml or cover letter
- Using vastly different dates on the form itself, in the cover letter and/or the eCTD us-regional.xml

Resources

- Form FDA 1571
- Instructions for Filling Out Form FDA 1571
- SOPP 8117: Issuing Submission Numbers in Advance of the Receipt of the Electronic Submission (CBER)
- Pre-assignment of CDER application numbers (CDER)

Resources

- Orphan Drugs and Rare Diseases (field 7)
- Development Safety Update Report (DSUR) (field 11)
- Submissions for evaluation of proprietary names (field 11)
- Final Rules for Expanded Access to Investigational Drugs for Treatment Use and Charging for Investigational Drugs (field 12)
- Biosimilars

Contact Information

Questions regarding electronic submissions should be sent to:

- CDER questions: esub@fda.hhs.gov
- CBER questions: esubprep@fda.hhs.gov

Contact Information

Further questions about the form that have not been answered during this Webinar should be directed to:

CDERSmallBusiness@fda.hhs.gov

(866)-405-5367 or (301)-796-6707

Industry.biologics@fda.hhs.gov

(800)-835-4709 or (301)-827-1800

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TIME FOR AUDIENCE Q&A