What's New with the 356h Form?

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What is the Form Used For?

- Accompanies regulatory submissions to new drug applications (NDAs), biologic license applications (BLAs), abbreviated new drug applications (ANDAs), and supplements
- Describes the reason for, and content of, the submission
- Captures information used to populate FDA systems

Why Was the Form Updated?

- New user fee programs: BsUFA, GDUFA, MDUFMA
- Need for additional tracking (e.g., rare disease information)
- 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?

- October 1, 2012 – release 1
- 2 more releases since 10/1 to make technical corrections and update or enhance certain fields (e.g., addition of countersignature field)
- Additional release tentatively planned in summer

What Was Updated?

- 508-compliant, fillable PDF
- Instructions, updated + now a separate document
- Designation of 351(a) vs 351(k) BLAs
- 505(b)(2) NDAs and ANDAs: specific patent certification(s) and/or statement are now captured
- Rare disease/orphan drug information now captured
- Establishment information section updated
- Addition of countersignature field
- Addition of continuation pages for establishment information, orphan drug designations, and cross references, as needed

LIVE WALK-THROUGH OF 356h FORM WITH MOCK DATA

FAQs – Establishment Info

- *Question*: Where should site contact information be captured?
- *Answer*: In the 'Manufacturing Steps, Type of Testing, and Site Contact Information' section of field 29. Please provide the name, phone number, fax, and email address for the contact at each manufacturing and testing facility utilized in the application.

FAQs – Establishment Info

- *Question*: What types of submissions require complete facility information in field 29?
- *Answer*: Original (initial) NDAs, BLAs, and ANDAs. Supplements (CMC and efficacy) and RSs of supplements should provide facility information in field 29 when there are changes, additions, or deletions to previously submitted facility information. Amendments to applications would indicate new and/or changed facility information specific to the amendment.

FAQs – Responsible Officials and US Agents

- *Question*: Whose contact information is intended in fields 32-37 and how does that relate to signature fields 38 and 39?
- *Answer*: The information captured in field 32 should be the name of the person responsible for the application, i.e., the applicant's responsible official certifying compliance with applicable laws and regulations. The person named in field 32 signs the form in field 38. For non-US applicants, an authorized U.S. agent must be designated in field 6; the agent can either sign the form as the applicant's responsible official in field 38 or provide the countersignature in field 39 if the responsible official resides outside the U.S.

FAQs – Version and Compatibility

- *Question*: Do I have to use the current version of the 356h form?
- *Answer*: Yes, ideally the current version should always be used so that important information can be captured and extracted to populate FDA systems.
- *Question*: What version(s) of Adobe Acrobat are compatible with the new fillable form?
- *Answer*: Adobe Acrobat 8 or 9. Currently, users with older versions of Acrobat may use previous versions of the form unless that version is no longer supported or accepted by FDA.

FAQs – Paper vs Electronic Submissions

- *Question*: How are electronic and paper submissions designated in fields 27 and 28 of this form?
- *Answer:*

For electronic/eCTD submissions sent via the Electronic Submission Gateway, select 'electronic' in field 27 and leave field 28 blank.

For mixed paper/electronic or an electronic only submission sent to the document room, select the appropriate box in field 27 and indicate the number of volumes contained within the submission in field 28. For electronic only submissions, the number of volumes entered in field 28 would most typically be '1'.

Note: FDA recommends including a paper copy of the cover letter and 356h form when submitting electronic media to the document room in case the media is damaged or can't be read.

Resources

- FDA Forms Web page
- Pre-assignment of CDER application numbers (field 7)
- Orphan Drugs and Rare Diseases (field 15)
- Biosimilars (fields 18-19)
- Generic drugs (fields 16, 20)
- 505(b)(2) applications (fields 17, 20)
- Registration and Listing (field 29)
- Submissions for evaluation of proprietary names

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
- (301)-796-6707

Questions regarding electronic submissions should be sent to:

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

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TIME FOR AUDIENCE Q&A