# Field 29 of 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 Field 29 Updated?

- Better tracking of facilities named in applications
- Allows for automated pull of facility data into FDA databases
- Accelerates facility reviews
- Embedded logic helps reduce number of errors submitted

# When Was Field 29 Updated?

- Revision to Field 29 initiated on 2/15/13
- Subsequent releases to make technical corrections and update or enhance certain fields
- Latest Release on 6/13/14

# *LIVE WALK-THROUGH OF 356h FORM WITH MOCK DATA*

# FAQs – Field 29

- *Question*: What types of submissions require complete facility information in field 29?
- *Answer*:
  - Original (initial) NDAs, BLAs, and ANDAs.
  - Supplements (CMC and efficacy)
  - Resubmissions of originals or supplements above
  - Amendments to applications where new and/or changed facility information is provided specific to the amendment.

# FAQs – Field 29

- *Question*: Which sites must be in field 29?
- *Answer*: The locations of all manufacturing, packaging, and control sites for both drug substance and drug product
  - Finished Dosage Form (FDF) Manufacturers
  - Active Pharmaceutical Ingredient (API) Manufacturers
  - Contract Testing Labs
    - That perform release testing for the API site
    - That perform release testing for the FDF site
  - Packaging and Labeling sites
  - Contract Manufacturers
    - API Micronizers
    - Terminal Sterilization Facilities

# FAQs – Field 29

- *Question*: What about excipient manufacturers?
- *Answer*:
  - Manufacturers of chemical intermediates, particularly those involved in manufacturing most synthesis steps to form the drug substance, should also be listed.
  - Excipient and container/closure manufacturing and control establishments do not need to be listed, however this information may be requested during review.

# The 356H form, Field 29 and the ANDA RTR Guidance

- The FDA Draft guidance for Refuse to Receive (RTR) standards can be found here:
  - http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM370352.pdf
- The guidance states the following:
  - "An application must contain a completed application form (i.e. Form FDA 356h). If this form is not included, FDA will refuse to receive the ANDA. The applicant should include all of the facility information that is listed in Modules 3.2.S.2 and 3.2.P.3.1 (drug substance and drug product, respectively) of the application in Field 29 of the 356h form, using continuation pages for Field 29 when needed."

# FAQs – Field 29

- *Question*: What does “ready for inspection” mean?
- *Answer*:
  - Review and planning for inspection begins when a submission is received. Therefore, establishments need to be ready for inspection so FDA can evaluate whether the site is able to reliably perform intended operation(s) at a commercial scale.
  - Regarding readiness for commercial manufacturing, you may refer to Compliance Program Guidance Manual 7346.832.

# FAQs – Field 29

- *Question*: What if a site is not ready for inspection?
- *Answer*:
  - All sites should be ready for inspection at the time of submission.
  - If a site is not ready, please indicate when it will be ready for inspection.
  - Note, if any site is not ready for inspection, FDA could Refuse to Receive (RTR) or Refuse to File (RTF) the application.

# FAQs – Field 29

- *Question*: When can N/A be used for "Is the site ready for inspection"?
- *Answer*:
  - The N/A option can only be used if a facility is:
  - Previously withdrawn or being withdrawn as part of the current submission.
  - Or the site is "Inactive"
    - Inactive sites should only be seen for supplements detailing approved facilities that are not currently performing application related functions, though they could resume them at a later date.

# FAQs – Field 29

- *Question*: What should I do if the site contact does not have a fax number?
- *Answer*:
  - Not all sites will have a fax number. The field on the form can accept text. Thus, if a site does not have a fax number, simply enter "N/A" in the field.

# FAQs – Field 29

- *Question*: What if a facility does not have a Master File (MF or DMF) associated with it?
- *Answer*:
  - Only certain facilities will have associated DMFs.
  - If a facility does not have a MF/DMF, leave this field blank.

# FAQs – Field 29

- *Question*: Where can I get a site's FEI and/or DUNS number?
- *Answer*:
  - Try this website:

    http://www.accessdata.fda.gov/scripts/cder/drls/default.cfm

  - If not on the website, the facility should be able to provide you its FEI and DUNs number.

# FAQs – Field 29

- *Question*: How can a facility find its DUNS number?
- *Answer*:
  - DUNS Numbers can be obtained, or DUNS information modified, through D&B using the basic service (no cost) http://www.dnbgov.com/federal_compliance/fda/DUNSrequest/requestGuide.html1
  - or using the expedited service (nominal fee) at http://www.dnbgov.com/federal_compliance/fda/DUNSrequest/

# FAQs – Field 29

- *Question*: How can a facility find its FEI number?
- *Answer*:
  - A business entity that has previously obtained an FEI number may verify its FEI number on FDA's registration site for drug establishments.
  - GDUFA related business entities that have not previously registered with FDA can obtain an FEI number by sending an email request to: FDAGDUFAFEIRequest@fda.hhs.gov .

# FAQs – Field 29

- *When you send and email to*

FDAGDUFAFEIRequest@fda.hhs.gov

- Please type “GDUFA FEI Request” in the subject line and include the following information in the body of the email:
  - Firm Name
  - Facility Address including City, Province, Country, and Mail Code
  - Size of Firm
  - Type of Operation (Manufacturer, Lab, etc.)
  - Type of Industry:  Drugs

# FAQs – Field 29

- *Question*: How can a facility obtain its FEI number?
- *Answer*:
  - For non GDUFA related business entities,
  - If located in the United States, please contact your local FDA ORA office
  - If located outside the US, send an email to: fdaforeignoeirequests@fda.hhs.gov

# FAQs – Field 29

- *Question*: Which facilities should be listed on the 356h form for combination products?
- *Answer*:
  - For combination products or drug products involving device components, applicants should include, in addition to the locations of all manufacturing, packaging, and control sites for the drug substance and drug product, the sites involved in device assembly for the commercial product.

# FAQs – Field 29

- *Question*: What if I have more facilities than the form can accommodate?
- *Answer*:
  - The current form can accommodate 31 individual facilities, so this should be rare
  - However, if such is the case, provide the remaining establishments in a similar tabular format as used on the form in a separate form attachment
  - The attachment should be referenced and placed in the same location as the 356h form
  - Please contact FDA for further questions regarding your particular situation.

# FAQs – Field 29

- *Question*: What should I put in the manufacturing steps section?
- *Answer*:
  - Provide a general description of all responsibilities the site is doing.
    - API Manufacture
    - API Release testing
    - Finished dosage manufacture
  - The more descriptive the better

# FAQs – Field 29

- *Question*: What facilities need to be submitted for supplements (CMC, efficacy)?
- *Answer*:
  - All facilities being utilized, whether previously approved or not.
  - Utilized the checkboxes related to “Is this facility new to the application” to delineate approved vs new sites.

# FAQs – Field 29

- *Question*: When submitting a supplement to add a new establishment, can I list only that new establishment on the 356h form?
- *Answer*:
  - No
  - All facilities (active, inactive, and withdrawn) should be listed on the form, and the new facility should be listed and marked “pending”.

# FAQs – Field 29

- *Question*: What if I can't find up to date contact information for facilities? How should we complete the form?
- *Answer*:
  - As a sponsor, it is your responsibility to know the contact information for all of the facilities (approved or pending) in your application.

# 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*: Should I 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.

# 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:

- CDERSBIA@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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# Acronyms

- FEI = Facility Establishment Identifier
- ORA = Office of Regulatory Affairs
- D&B = Dun & Bradstreet
- CMC = Chemistry, Manufacturing, and Controls
- NDA, ANDA = New Drug Application, Abbreviated New Drug Application
- BLA = Biologics License Application
- API = Active Pharmaceutical Ingredient
- FDF = Finished Dosage Form
- RTR/RTF = Refuse to Receive/Refuse to File
- DMF/MF = Drug Master File/Master File

# *TIME FOR AUDIENCE Q&A*