Regulatory Submissions, Information, and Document Management Forum

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#RSIDM22
FDA Forms Update

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Agenda

- Background
- General Forms Questions
- Challenges with Forms 356h & 1571
- New Form: 3938 for Drug Master Files (DMF)
- Common Questions for Other Forms:
  - Form 3926
  - Forms 3542a & 3542
- Resources
Background

- Regulatory forms are an integral part of FDA’s submission process
- Forms have evolved in response to legislation, regulatory requirements, industry, and new technology
- More recently, fillable PDF forms were introduced to provide machine readable information that can be extracted and compared against other data sources
- FDA leverages form data to obtain administrative information, help determine review types, milestones, regulatory commitments, etc.

The 356h Form was significantly updated in 1996 to harmonize between CDER & CBER and replace several other forms
General Form Questions

- Where do I find the latest versions of FDA regulatory forms?
  The latest version are available on the FDA Forms webpage, https://www.fda.gov/about-fda/reports-manuals-forms/forms.

- Forms aren’t opening/downloading, it says “please wait” when I try to open it. What should I do?
  In order to avoid potential issues, it is recommended to download the form and use the saved version to fill out the form in Adobe rather from a browser.

- Can we still use an expired form?
  Yes, forms posted on the FDA Forms webpage can be used until instructed otherwise.

- I am not able to digitally sign a form in Adobe. What should I do?
  Make sure all required fields are filled out. If there are still issues, submit both an unsigned fillable form and a hand signed scanned form with a wet signature. See https://www.fda.gov/industry/policiesguidance/important-information-about-digitalelectronic-signatures for more detail on form signatures.
Challenges with Existing Forms: 356h and 1571
Challenges

- Discrepancies in forms data or incorrect use of fields increase manual processing
- Reuse of forms by Sponsors can cause extraneous or incorrect information to be passed to FDA
- Not providing information for all applicable fields results in additional efforts and could impact the review process
### 356h Form Challenges Examples

**PRODUCT DESCRIPTION**

<table>
<thead>
<tr>
<th>7. NOA, ANDA, or BLA Application Number</th>
<th>8. Supplement Number (If applicable)</th>
</tr>
</thead>
</table>

9. Established Name (e.g., proper name, USP/USAN name)

**Established (non-proprietary) Name and/or Proprietary Name contain:**

- [X] Dosage
- [X] Strength
- [X] Route of Administration

10. Proprietary Name (Trade Name) (If any)

11. Chemical/biochemical/blood Product Name (If any)

12. Dosage Form

13. Strengths

14. Route of Administration

15A. Proposed Indication for Use

- Is this indication for a rare disease (prevalence <200,000 in U.S.)? Yes □ No □

**Fields 12, 13, and 14 are intended to capture dosage, strength, and ROA information**
### 356h Form Challenges Examples (Cont’d)

<table>
<thead>
<tr>
<th>PRODUCT DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>7. NOA, ANDA, or BLA Application Number</td>
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</tr>
<tr>
<td>10. Proprietary Name (Trade Name) (If any)</td>
</tr>
<tr>
<td>11. Chemical/Biochemical/Blood Product Name (If any)</td>
</tr>
<tr>
<td>12. Dosage Form</td>
</tr>
<tr>
<td>14. Route of Administration</td>
</tr>
</tbody>
</table>

- **Orphan Designation selected but no Designation Number included**
- **Route of Administration contains percentages**

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*www.fda.gov*
356h & 1571 Form Challenges Examples

Form 356h:

- Address line 1 left blank and address line 2 contains full address information
- Address contains full address, including city, state, etc.
- Missing address with only city state and zip code

Form 1571:

- Address information should be provided starting in the field, Address 1, and City, State, Country and Zip Code should be provided in separate fields
Inconsistent Data for SNOMED Code and Descriptions in 7A and 7B

In 7B provide the SNOMED CT coded disease term for the indication provided in Field 7A

- Example: 38341003 | Hypertensive disorder, systemic arterial (disorder)
- SNOMED CT coded disease terms can be found here: http://browser.ihtsdotools.org/
New Form: 3938 for Drug Master Files
Form 3938

- Available since August 2021
- Provides standardized and structured format to enable automated processing of DMF information by FDA systems
- Refer to https://www.fda.gov/drugs/forms-submission-requirements/drug-master-files-dmfs for more information on DMF and related submission resources
Common Questions about Form 3938

- Where can I access the form?
  The form is available at both FDA Forms and DMF webpages referenced in the previous slides.

- Will my submission be rejected if I do not provide 3938?
  You are encouraged to include Form 3938 in your DMF submission, but at this point it won’t be rejected if you do not.

- Where should the form go in eCTD structure?
  It goes under the 1.1 forms section. If your eCTD publishing tool has not yet been updated for the new form, it can place it under the 1.2 cover letting heading as an alternative.

- What should I enter in a required address field which does not apply to me, for example State/Province/Region?
  You can enter “NA”.

- I do not have DUNS or FEI Number available at time of submission. What number should I provide?
  If DUNS or FEI number is unknown or not available, enter “999999999” (9-digits) in the DUNS field and “9999999999” (10-digits) in the FEI field.
Common Questions for Other Forms

- Form 3926
- Forms 3542a & 3542
Common Questions about Form 3926

- **What is the purpose of Form 3926?**
  
  Form 3926 is designed to provide a streamlined alternative for submitting an Investigational New Drug Application (IND) for use in cases of individual patient expanded access, including for emergency use.

- **How do I fill out Form 3926?**
  
  The form should be downloaded and filled out electronically in Adobe. Please do not use internet browser for filling out the form.

- **How should I submit Form 3926?**
  
  Refer to [https://www.fda.gov/news-events/expanded-access/expanded-access-how-submit-request-forms](https://www.fda.gov/news-events/expanded-access/expanded-access-how-submit-request-forms) for the address and submission options. The Form should **not** be submitted to the FDA PRA staff.
Common Questions about Forms 3542a and 3542

What is the purpose of Forms 3542a and 3542?

- Form 3542a is submitted with original unapproved New Drug Application (NDA), amendment, or supplement
- Form 3542 is submitted within 30 days after NDA or supplement approval or within 30 days of issuance of patent

Where can I access the most recent versions of these forms?

The most recent versions expiring in 2024 are available on the FDA Forms webpage.

What should I include in the form title?

To support automated processing by FDA systems please make sure to include “Form 3542” or “Form 3542a” as part of the form pdf file or eCTD title.

Can I submit multiple patent forms as part of one file?

Please submit only one patent per file as combining multiple patent forms into one file makes reviewing the forms difficult. Note that the earlier deficient form doesn't count as a previous submission.
Resources

❖ FDA Forms webpage:
  https://www.fda.gov/about-fda/reports-manuals-forms/forms

❖ Forms and Submission Requirements:
  https://www.fda.gov/drugs/development-approval-process-drugs/forms-submission-requirements

❖ Questions?
  Contact CDER Division of Drug Information U.S. Food and Drug Administration druginfo@fda.hhs.gov or the contacts listed on FDA Forms webpage