Regulatory Submissions, Information, and Document Management Forum

February 14-16
North Bethesda, MD

#RSIDM22

FDA Forms Update

Daniil Graborov
Office of Business Informatics
Center for Drug Evaluation and Research

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The views and opinions presented here represent those of the speaker and should not be considered to represent advice or guidance on behalf of the U.S. Food and Drug Administration.

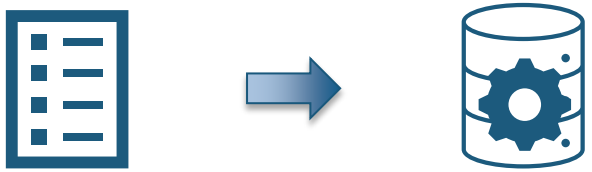
Agenda

- 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

FDA Forms

Background

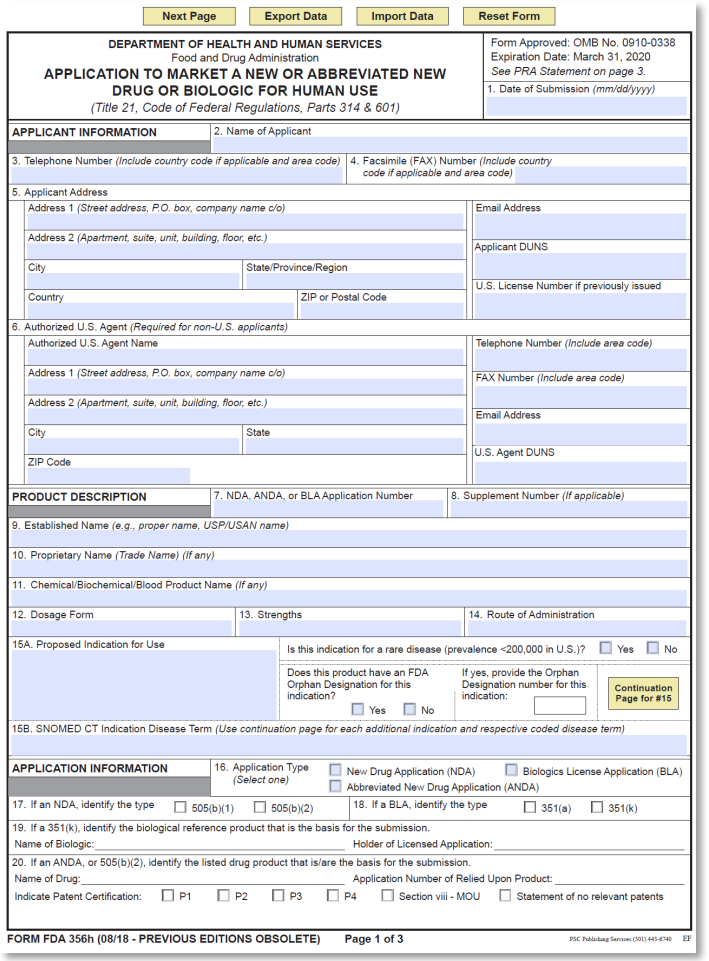
- Regulatory forms are an integral part of FDA's submission process
- Forms have evolved in response to legislation, regulatory requirements, industry, and new technology
- More recently, fillable PDF forms were introduced to provide machine readable information that can be extracted and compared against other data sources



Regulatory Forms → **Submission Processing**

- 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



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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
APPLICATION TO MARKET A NEW OR ABBREVIATED NEW DRUG OR BIOLOGIC FOR HUMAN USE
(Title 21, Code of Federal Regulations, Parts 314 & 601)

Form Approved: OMB No. 0910-0338
Expiration Date: March 31, 2020
See PRA Statement on page 3.

1. Date of Submission *(mm/dd/yyyy)*

APPLICANT INFORMATION

2. Name of Applicant
3. Telephone Number *(Include country code if applicable and area code)*
4. Facsimile (FAX) Number *(Include country code if applicable and area code)*
5. Applicant Address
Address 1 *(Street address, P.O. box, company name c/o)*
Address 2 *(Apartment, suite, unit, building, floor, etc.)*
City | State/Province/Region | Country | ZIP or Postal Code
Email Address | Applicant DUNS | U.S. License Number if previously issued
6. Authorized U.S. Agent *(Required for non-U.S. applicants)*
Authorized U.S. Agent Name
Address 1 *(Street address, P.O. box, company name c/o)*
Address 2 *(Apartment, suite, unit, building, floor, etc.)*
City | State | ZIP Code
Telephone Number *(Include area code)* | FAX Number *(Include area code)* | Email Address | U.S. Agent DUNS

PRODUCT DESCRIPTION

7. NDA, ANDA, or BLA Application Number | 8. Supplement Number *(If applicable)*
9. Established Name *(e.g., proper name, USP/USAN name)*
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
Does this product have an FDA Orphan Designation for this indication? ☐ Yes ☐ No
If yes, provide the Orphan Designation number for this indication:
Continuation Page for #15
15B. SNOMED CT Indication Disease Term *(Use continuation page for each additional indication and respective coded disease term)*

APPLICATION INFORMATION

16. Application Type *(Select one)* ☐ New Drug Application (NDA) ☐ Biologics License Application (BLA) ☐ Abbreviated New Drug Application (ANDA)
17. If an NDA, identify the type ☐ 505(b)(1) ☐ 505(b)(2)
18. If a BLA, identify the type ☐ 351(a) ☐ 351(k)
19. If a 351(k), identify the biological reference product that is the basis for the submission.
Name of Biologic: _____ Holder of Licensed Application: _____
20. If an ANDA, or 505(b)(2), identify the listed drug product that is/are the basis for the submission.
Name of Drug: _____ Application Number of Relied Upon Product: _____
Indicate Patent Certification: ☐ P1 ☐ P2 ☐ P3 ☐ P4 ☐ Section viii - MOU ☐ Statement of no relevant patents

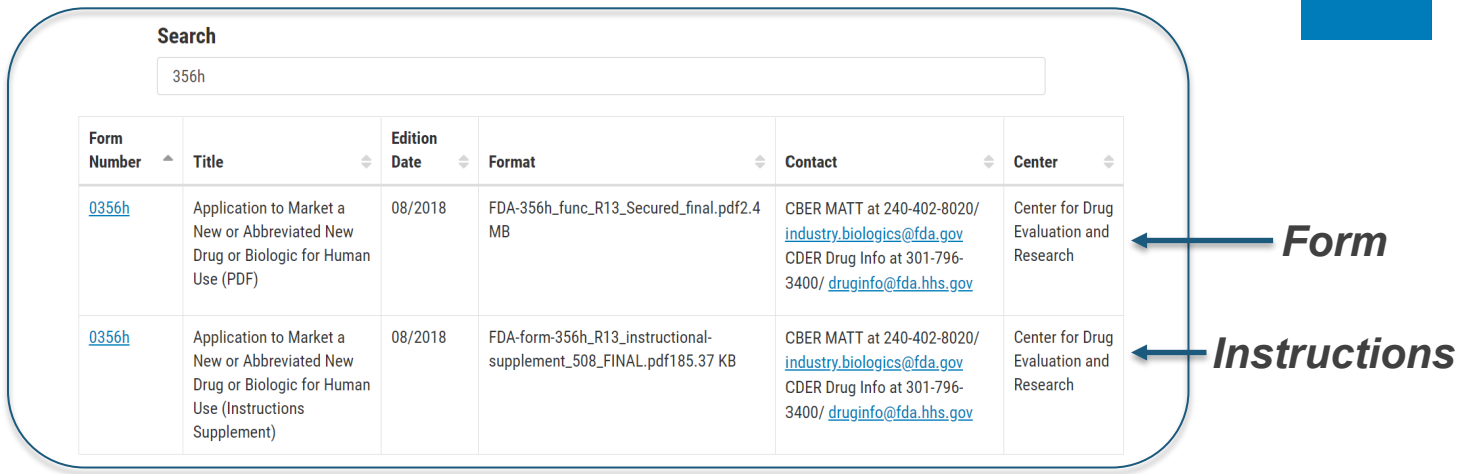
FORM FDA 356h (08/18 - PREVIOUS EDITIONS OBSOLETE) Page 1 of 3 PSC Publishing Services (301) 443-6740 EF

General Form Questions

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?**

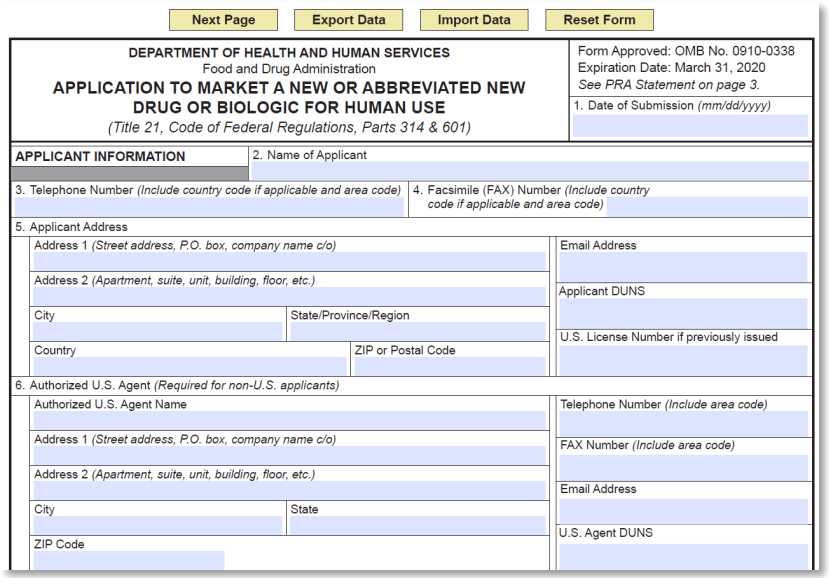
  Make sure all required fields are filled out. If there are still issues, submit both an unsigned fillable form and a hand signed scanned form with a wet signature. See https://www.fda.gov/industry/policiesguidance/important-information-about-digitalelectronic-signatures for more detail on form signatures.

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

Form FDA 356h:



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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
APPLICATION TO MARKET A NEW OR ABBREVIATED NEW DRUG OR BIOLOGIC FOR HUMAN USE
(Title 21, Code of Federal Regulations, Parts 314 & 601)

Form Approved: OMB No. 0910-0338
Expiration Date: March 31, 2020
See PRA Statement on page 3.

1. Date of Submission (mm/dd/yyyy)

APPLICANT INFORMATION

2. Name of Applicant

3. Telephone Number (Include country code if applicable and area code)

4. Facsimile (FAX) Number (Include country code if applicable and area code)

5. Applicant Address

Address 1 (Street address, P.O. box, company name c/o)

Address 2 (Apartment, suite, unit, building, floor, etc.)

City | State/Province/Region | Country | ZIP or Postal Code

Email Address

Applicant DUNS

U.S. License Number if previously issued

6. Authorized U.S. Agent (Required for non-U.S. applicants)

Authorized U.S. Agent Name

Address 1 (Street address, P.O. box, company name c/o)

Address 2 (Apartment, suite, unit, building, floor, etc.)

City | State | ZIP Code

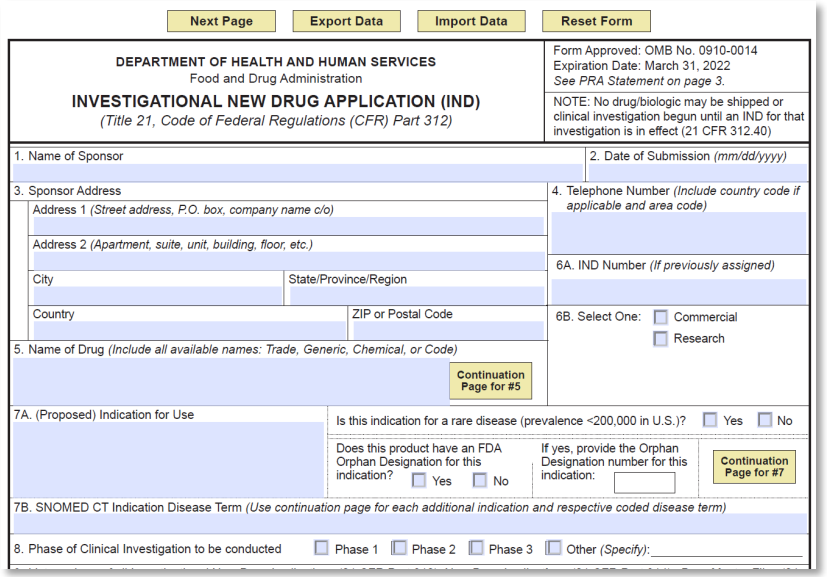
Telephone Number (Include area code)

FAX Number (Include area code)

Email Address

U.S. Agent DUNS

Form FDA 1571:



Next Page | Export Data | Import Data | Reset Form

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
INVESTIGATIONAL NEW DRUG APPLICATION (IND)
(Title 21, Code of Federal Regulations (CFR) Part 312)

Form Approved: OMB No. 0910-0014
Expiration Date: March 31, 2022
See PRA Statement on page 3.

NOTE: No drug/biologic may be shipped or clinical investigation begun until an IND for that investigation is in effect (21 CFR 312.40)

1. Name of Sponsor

2. Date of Submission (mm/dd/yyyy)

3. Sponsor Address

Address 1 (Street address, P.O. box, company name c/o)

Address 2 (Apartment, suite, unit, building, floor, etc.)

City | State/Province/Region | Country | ZIP or Postal Code

4. Telephone Number (Include country code if applicable and area code)

6A. IND Number (If previously assigned)

6B. Select One: Commercial Research

5. Name of Drug (Include all available names: Trade, Generic, Chemical, or Code)

Continuation Page for #5

7A. (Proposed) Indication for Use

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

Does this product have an FDA Orphan Designation for this indication? Yes No

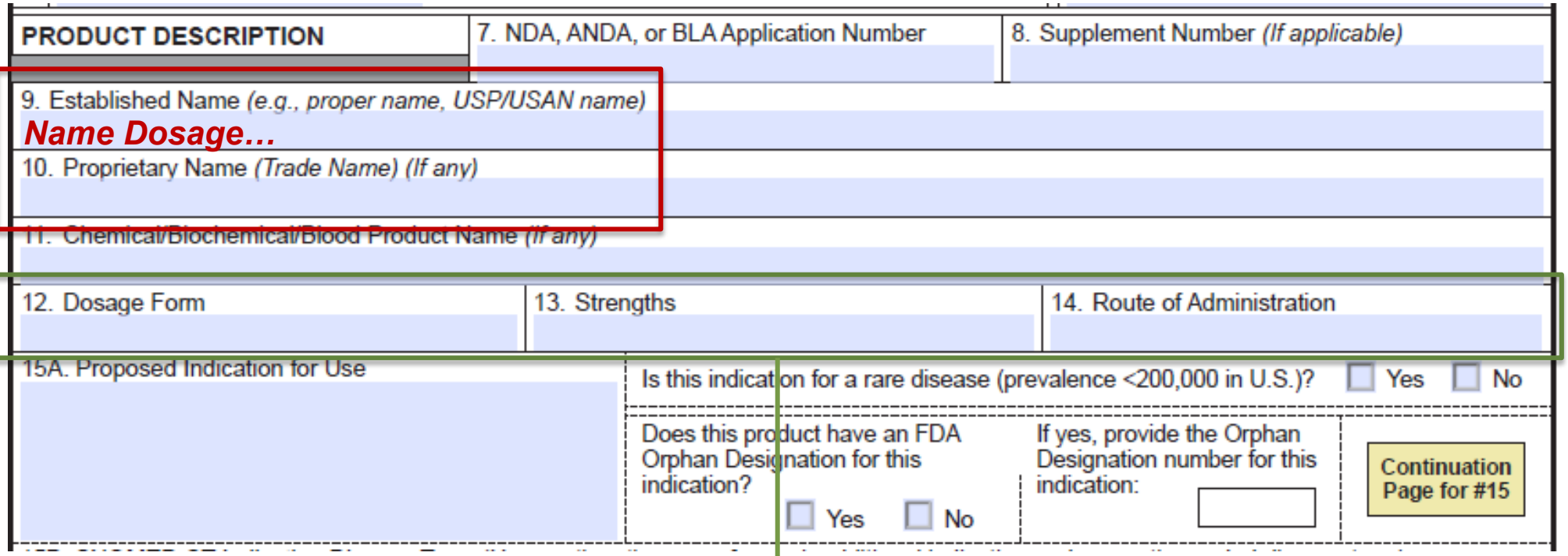
If yes, provide the Orphan Designation number for this indication:

Continuation Page for #7

7B. SNOMED CT Indication Disease Term (Use continuation page for each additional indication and respective coded disease term)

8. Phase of Clinical Investigation to be conducted Phase 1 Phase 2 Phase 3 Other (Specify):

356h Form Challenges Examples



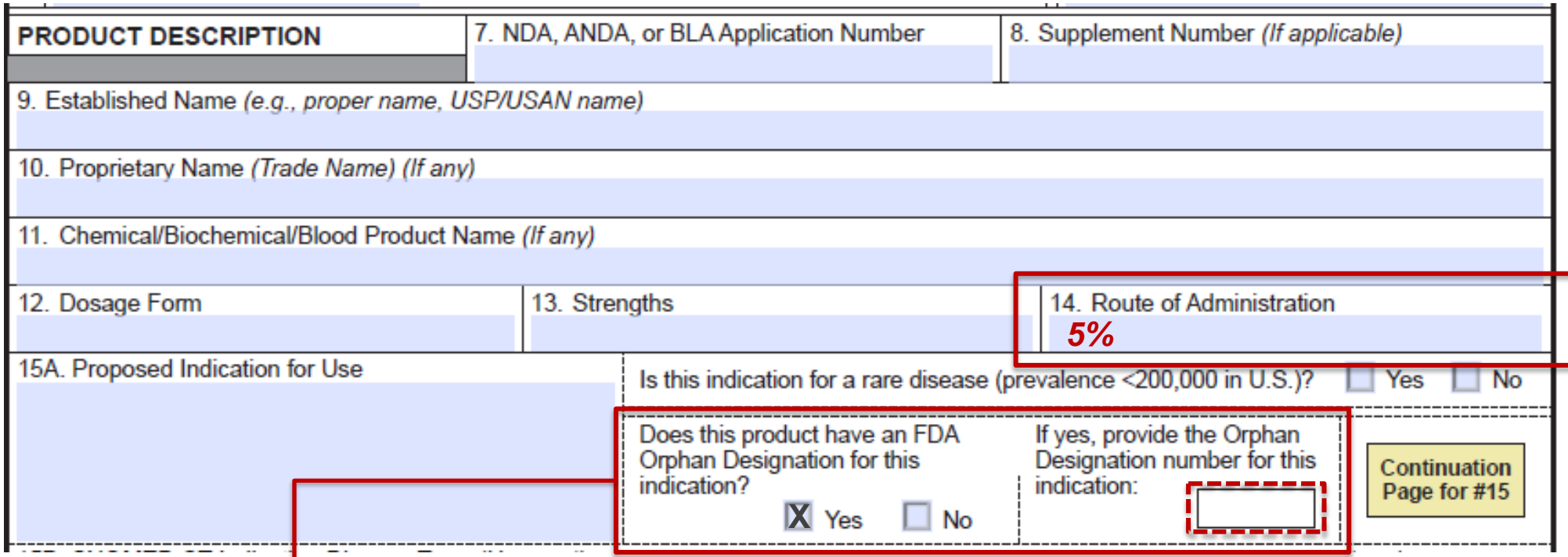
PRODUCT DESCRIPTION	7. NDA, ANDA, or BLA Application Number	8. Supplement Number *(If applicable)*
9. Established Name *(e.g., proper name, USP/USAN name)*		
Name Dosage…		
10. Proprietary Name *(Trade Name) (If any)*		
11. Chemical/Biochemical/Blood Product Name *(If any)*		
12. Dosage Form	13. Strengths	14. Route of Administration
15A. Proposed Indication for Use	Is this indication for a rare disease (prevalence <200,000 in U.S.)? ☐ Yes ☐ No	
	Does this product have an FDA Orphan Designation for this indication? ☐ Yes ☐ No	If yes, provide the Orphan Designation number for this indication: ☐
		Continuation Page for #15

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

- X **Dosage**
- X **Strength**
- X **Route of Administration**

✓ **Fields 12, 13, and 14 are intended to capture dosage, strength, and ROA information**

356h Form Challenges Examples (Cont'd)



PRODUCT DESCRIPTION	7. NDA, ANDA, or BLA Application Number	8. Supplement Number *(If applicable)*
9. Established Name *(e.g., proper name, USP/USAN name)*		
10. Proprietary Name *(Trade Name) (If any)*		
11. Chemical/Biochemical/Blood Product Name *(If any)*		
12. Dosage Form	13. Strengths	14. Route of Administration *5%*
15A. Proposed Indication for Use	Is this indication for a rare disease (prevalence <200,000 in U.S.)? ☐ Yes ☐ No	
	Does this product have an FDA Orphan Designation for this indication? ☒ Yes ☐ No	If yes, provide the Orphan Designation number for this indication:

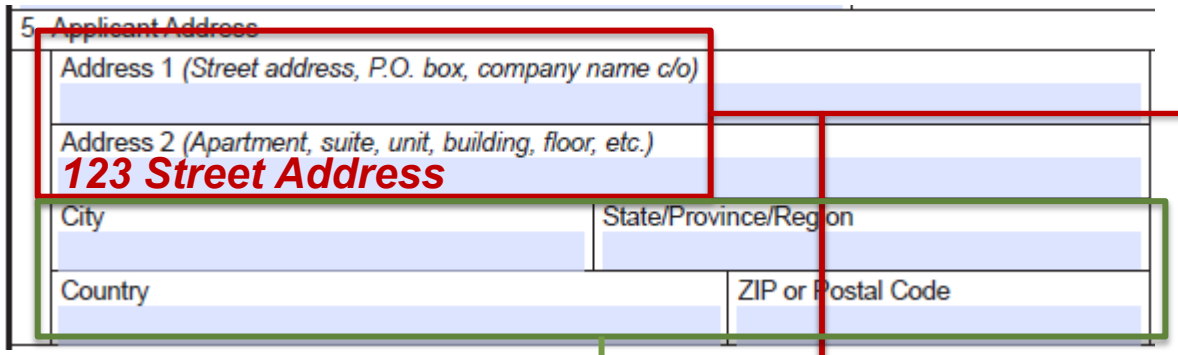
Continuation Page for #15

X **Orphan Designation selected but no Designation Number included**

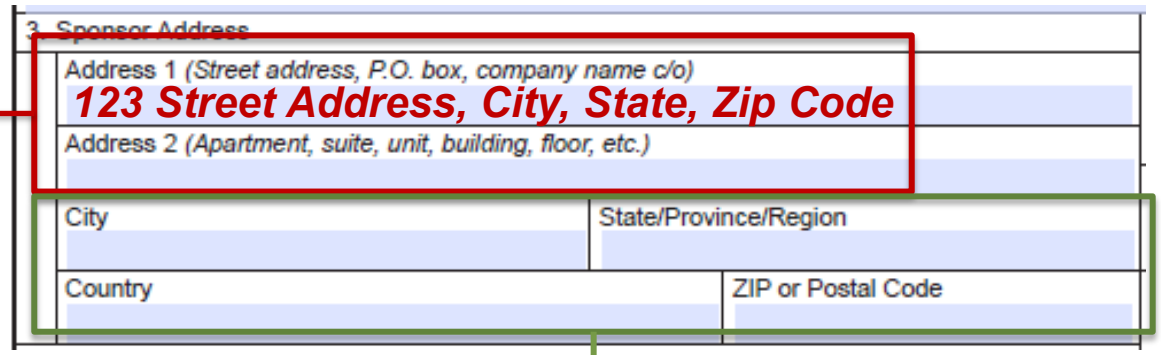
X **Route of Administration contains percentages**

356h & 1571 Form Challenges Examples

Form 356h:



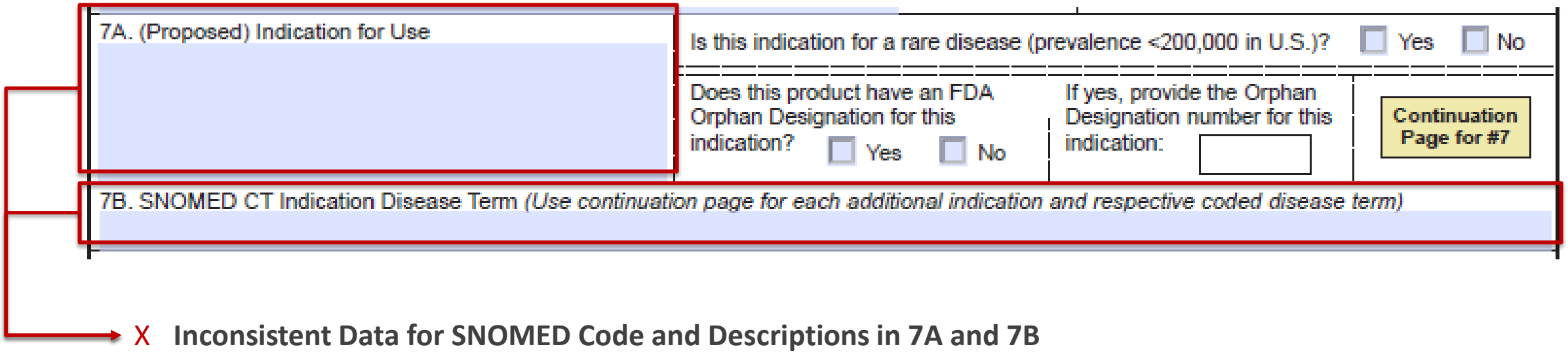
Form 1571:



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

- ✓ **Address information should be provided starting in the field, Address 1, and City, State, Country and Zip Code should be provided in separate fields**

1571 Form Challenges Example



X **Inconsistent Data for SNOMED Code and Descriptions in 7A and 7B**

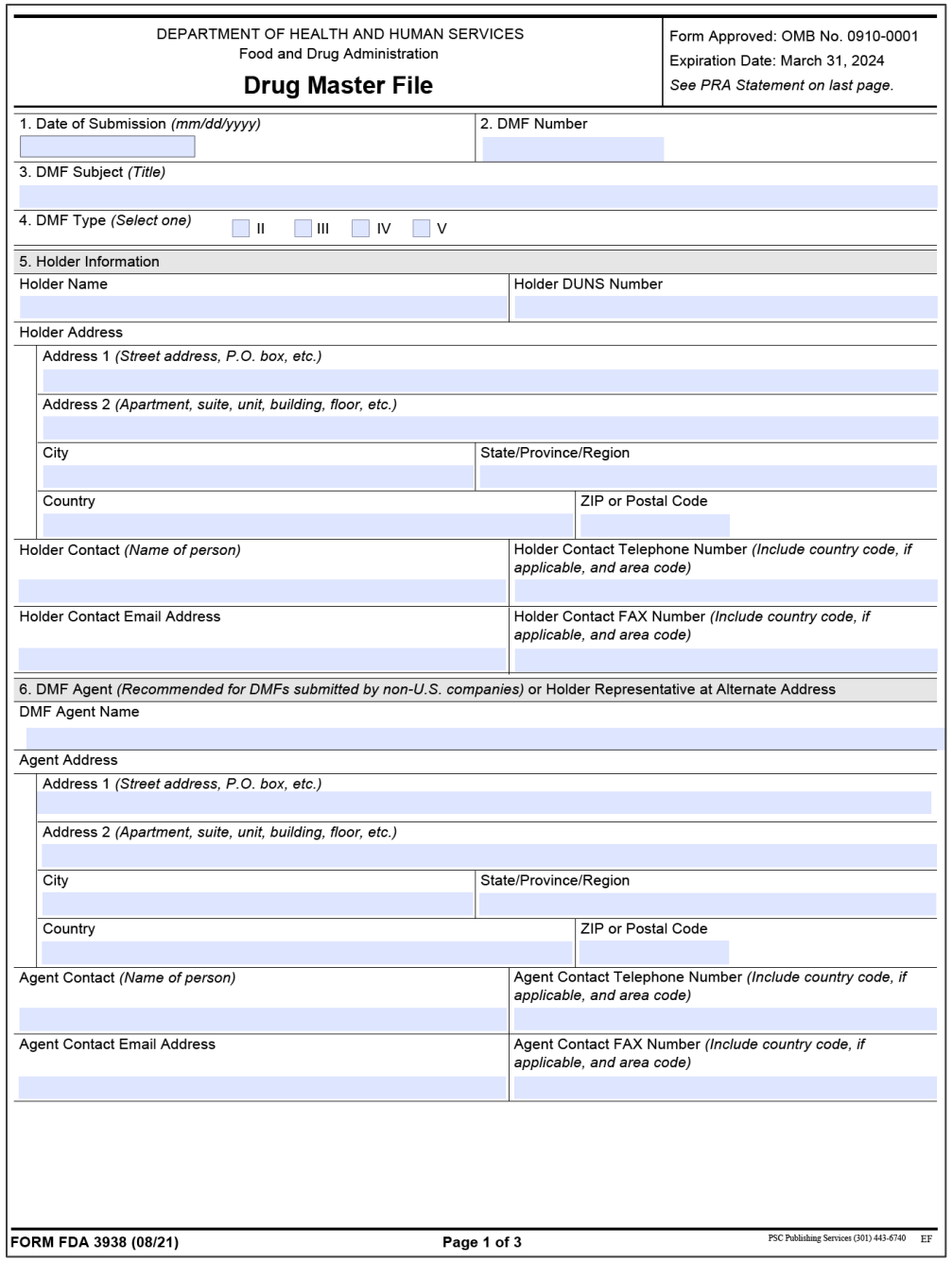
✓ **In 7B provide the SNOMED CT coded disease term for the indication provided in Field 7A**

- 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



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Drug Master File

Form Approved: OMB No. 0910-0001
Expiration Date: March 31, 2024
See PRA Statement on last page.

1. Date of Submission *(mm/dd/yyyy)*
2. DMF Number
3. DMF Subject *(Title)*
4. DMF Type *(Select one)* ☐ II ☐ III ☐ IV ☐ V

5. Holder Information

Holder Name
Holder DUNS Number
Holder Address
Address 1 *(Street address, P.O. box, etc.)*
Address 2 *(Apartment, suite, unit, building, floor, etc.)*
City
State/Province/Region
Country
ZIP or Postal Code
Holder Contact *(Name of person)*
Holder Contact Telephone Number *(Include country code, if applicable, and area code)*
Holder Contact Email Address
Holder Contact FAX Number *(Include country code, if applicable, and area code)*

6. DMF Agent *(Recommended for DMFs submitted by non-U.S. companies)* or Holder Representative at Alternate Address

DMF Agent Name
Agent Address
Address 1 *(Street address, P.O. box, etc.)*
Address 2 *(Apartment, suite, unit, building, floor, etc.)*
City
State/Province/Region
Country
ZIP or Postal Code
Agent Contact *(Name of person)*
Agent Contact Telephone Number *(Include country code, if applicable, and area code)*
Agent Contact Email Address
Agent Contact FAX Number *(Include country code, if applicable, and area code)*

FORM FDA 3938 (08/21) Page 1 of 3 PSC Publishing Services (301) 443-6740 EF

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?

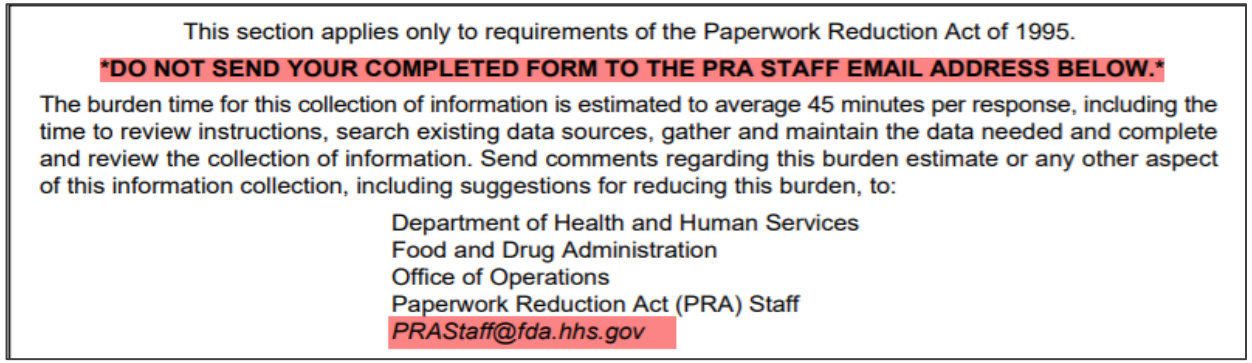
Form 3926 is designed to provide a streamlined alternative for submitting an Investigational New Drug Application (IND) for use in cases of individual patient expanded access, including for emergency use.

❖ 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 for the address and submission options.
*The Form should **not** be submitted to the FDA PRA staff*



This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 45 minutes per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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