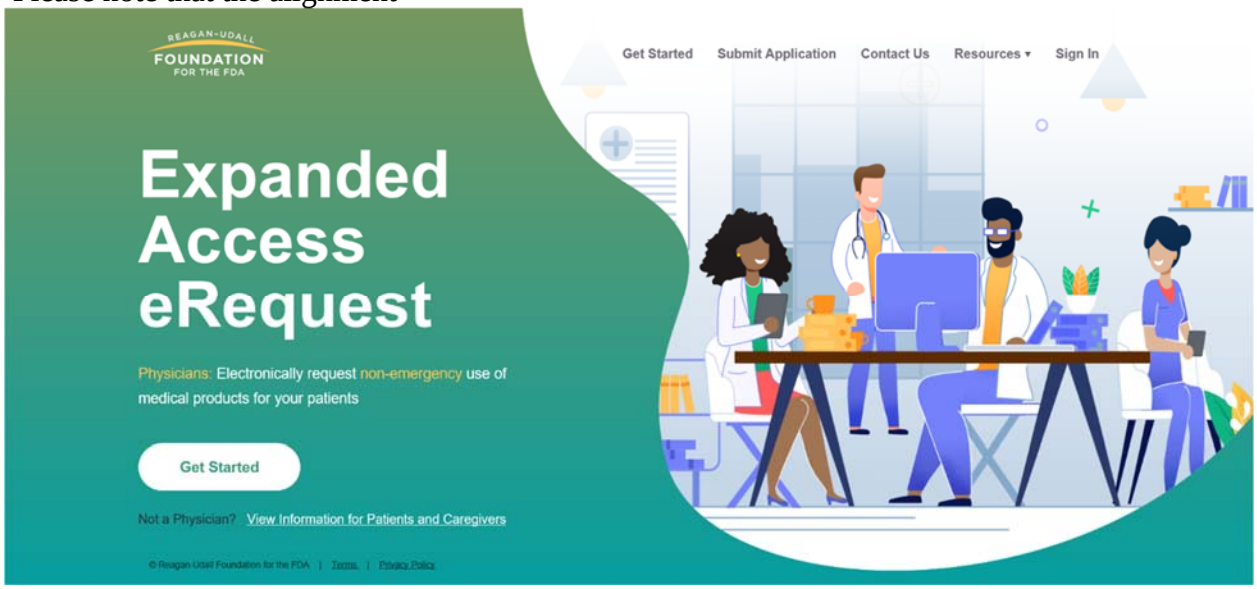
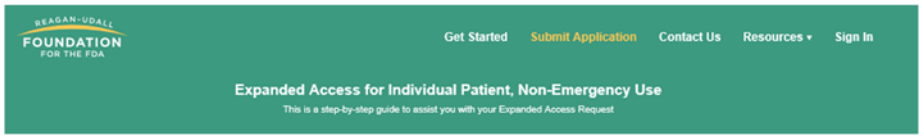
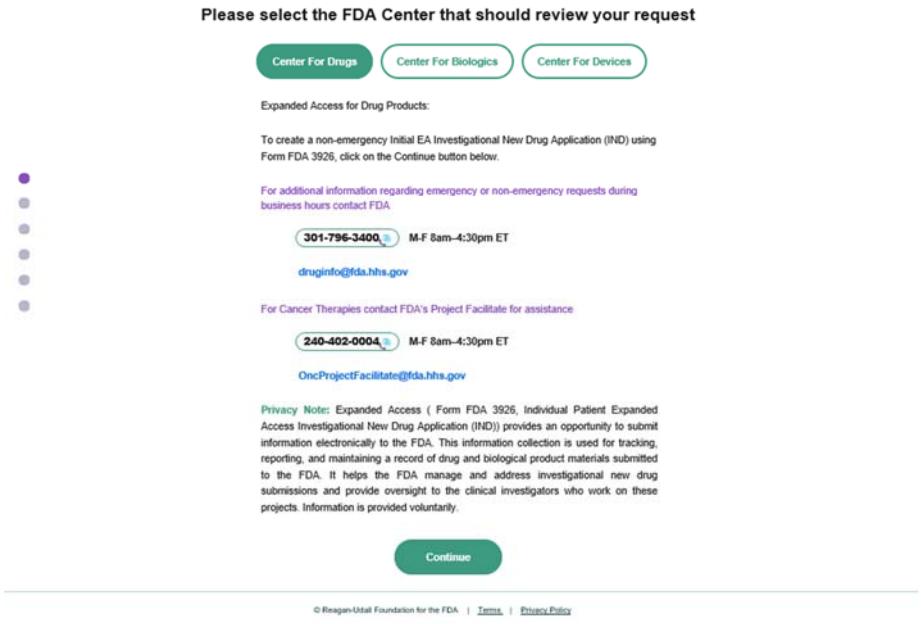
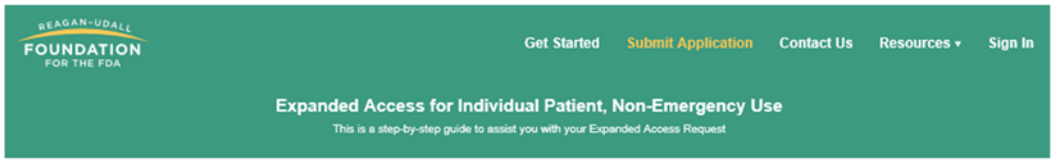
Screenshots for 0910-0814 User App:

Please note that the alignment







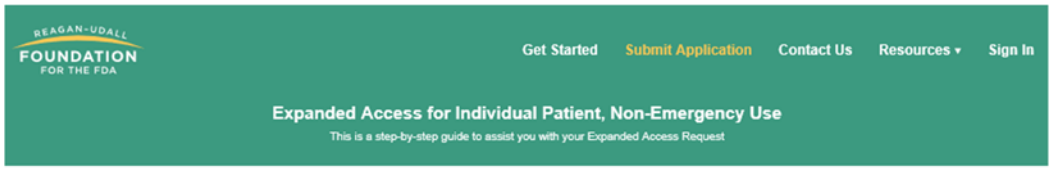


Is your patient eligible for a clinical trial?

Look for ongoing clinical trials on ClinicalTrials.gov. If your patient is eligible to participate in a clinical trial, please pursue enrollment in the trial.

Click 'Continue' if your patient is not eligible for a clinical trial.

Continue



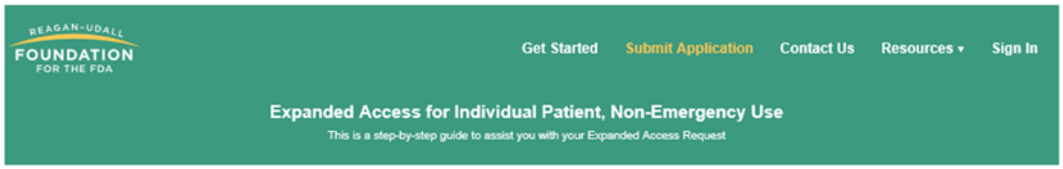
Is there already an Expanded Access Program or Protocol in place to treat the condition your patient has?

The Reagan-Udall Foundation's Expanded Access Navigator Company Directory provides EA policies and contact information for many drug and biological products manufacturers.

You can also check for existing Expanded Access program or protocol on ClinicalTrials.gov and type "expanded access" into the "Other Terms" field.

Click 'Continue' even if no prior Expanded Access program or protocol is found.

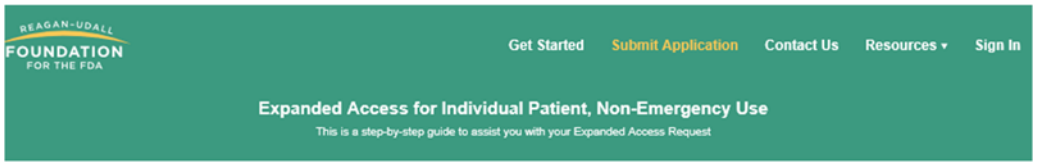
Continue



Have you identified an IRB for reviewing the treatment plan and Informed Consent document?

- Identify an Institutional Review Board (IRB) to review your proposed treatment plan and informed consent
- Find registered IRBs in your area through the Expanded Access Navigator
- Obtain approval from an IRB before treatment begins
  - Some Individual patient expanded access may only need concurrence by the IRB Chair or another member of the IRB
- Obtain the patient's Informed Consent before treatment begins

Continue



Do you have a Letter of Authorization (LOA) from the Manufacturer or Chemistry, Manufacturing, and Controls (CMC) Information?

You must have permission from the company that makes the drug/biological products to use it for EA. Additionally, a Letter of Authorization (LOA) lets FDA reference another application (IND) as FDA reviews your EA request. If you intend to use a biological product that you have manufactured or for which FDA does not have information on file, CMC information will need to accompany your application.

If you don't have an LOA yet, please read the information below

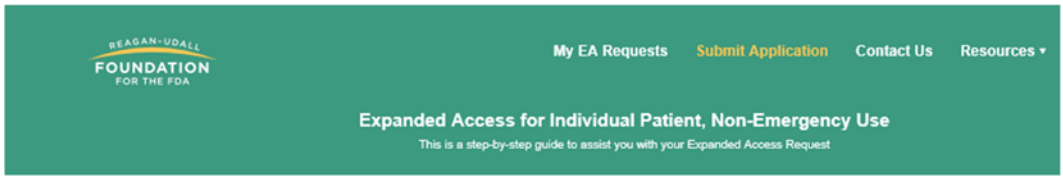
Directions on how to request expanded access: Expanded Access Navigator

For Company contact information:
Expanded Access Navigator Company Directory
If you do not find the company on the Reagan-Udall Foundation site, you can also search ClinicalTrials.gov

To see an example of wording for an LOA to send to the company, click here.

You may continue with the application submission process for now even if you don't have the LOA or CMC information. However, you will need the LOA (or, if requesting certain biological products, CMC information) for final submission.

Continue

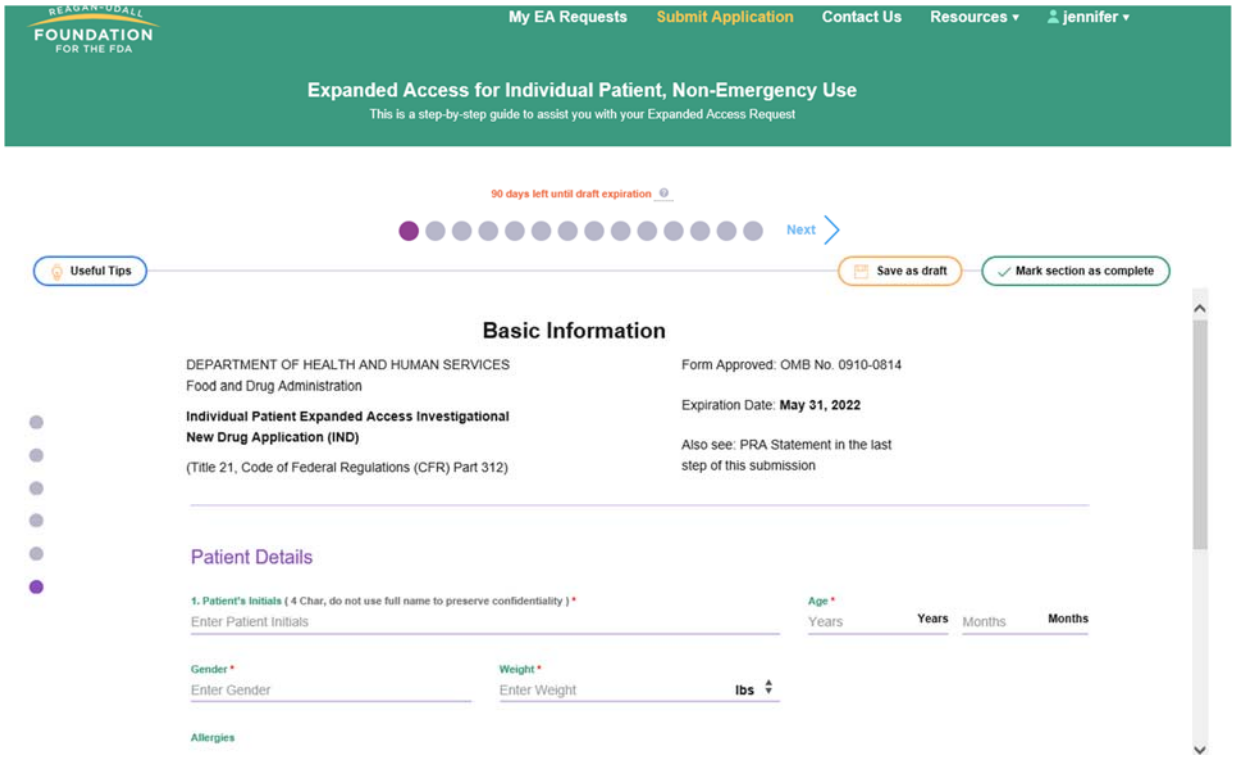


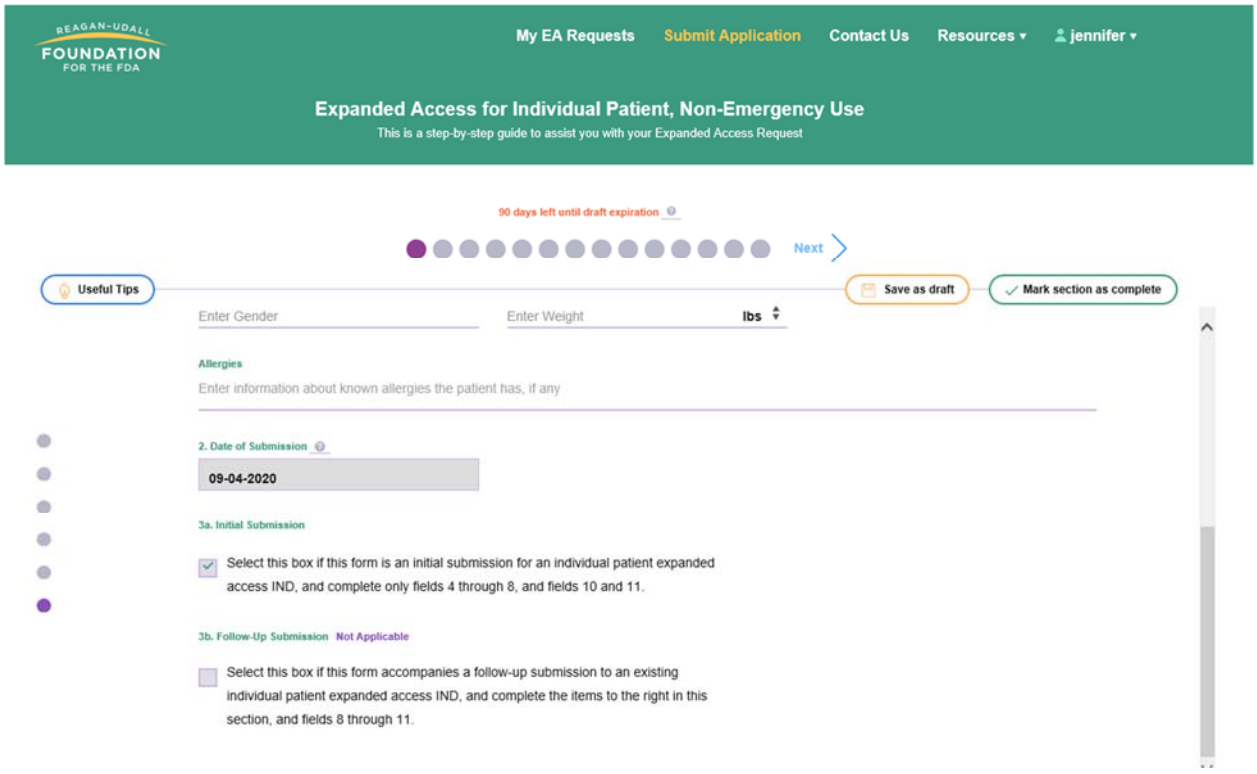
Fill In and Submit Form FDA 3926

Make sure you have the following information handy to complete Form FDA 3926 and your Expanded Access request:

- ✓ Your Information (ensure your profile information is up-to-date)
- ✓ Patient and drug/biological products information
- ✓ Letter of Authorization from the manufacturing company (or, if requesting certain biological products, Chemistry, Manufacturing, and Controls information)

Proceed To Form 3926

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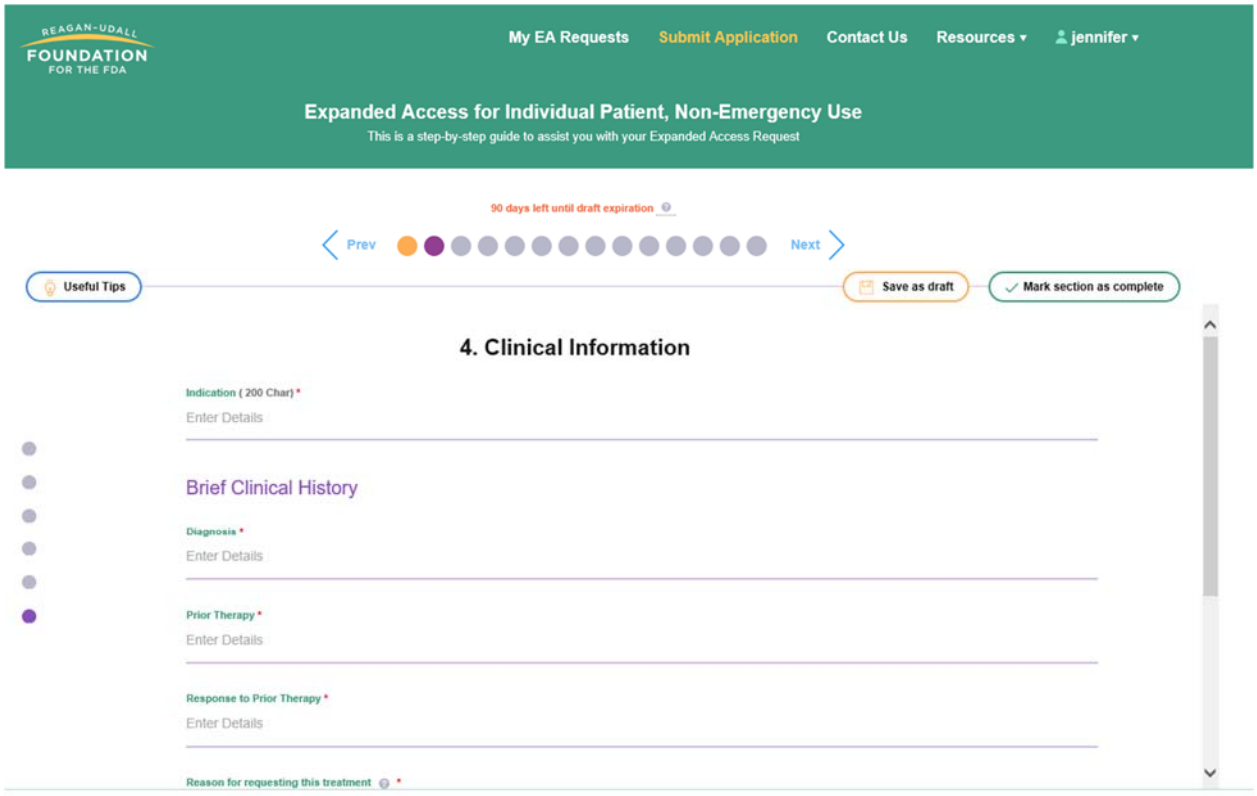
Mark section as complete
Enter Gender
Enter Weight
lbs
Allergies
Enter information about known allergies the patient has, if any
2. Date of Submission
09-04-2020
3a. Initial Submission
Select this box if this form is an initial submission for an individual patient expanded access IND, and complete only fields 4 through 8, and fields 10 and 11.
3b. Follow-Up Submission Not Applicable
Select this box if this form accompanies a follow-up submission to an existing individual patient expanded access IND, and complete the items to the right in this section, and fields 8 through 11.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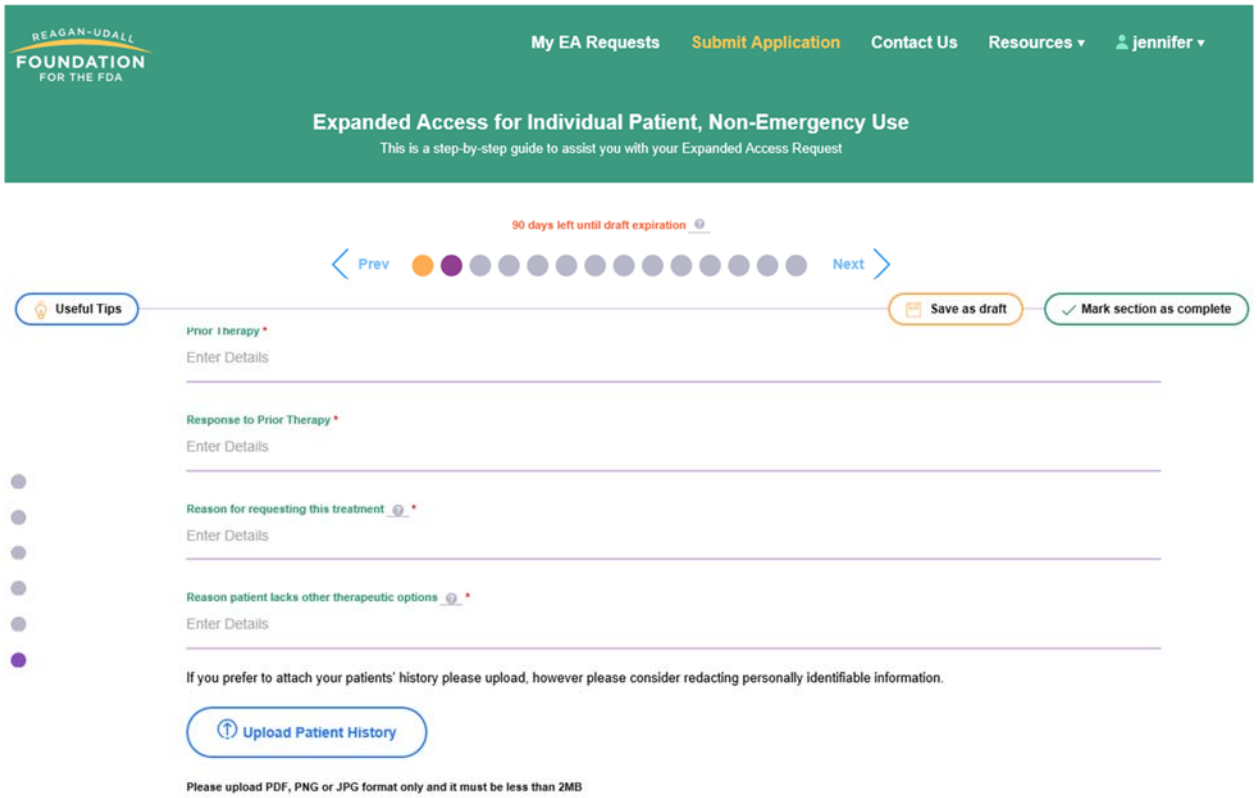
4. Clinical Information
Indication (200 Char) *
Enter Details
Brief Clinical History
Diagnosis *
Enter Details
Prior Therapy *
Enter Details
Response to Prior Therapy *
Enter Details
Reason for requesting this treatment *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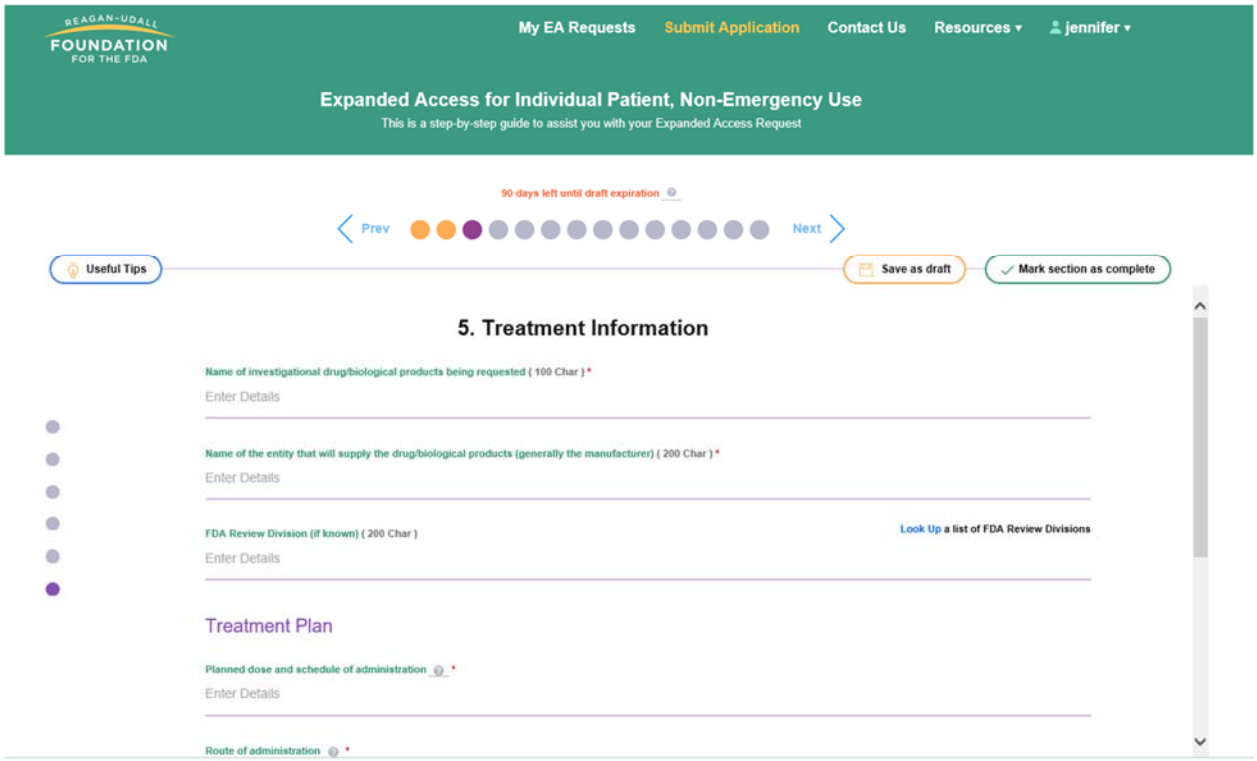
Mark section as complete
Prior Therapy *
Enter Details
Response to Prior Therapy *
Enter Details
Reason for requesting this treatment *
Enter Details
Reason patient lacks other therapeutic options *
Enter Details
If you prefer to attach your patients' history please upload, however please consider redacting personally identifiable information.
Upload Patient History
Please upload PDF, PNG or JPG format only and it must be less than 2MB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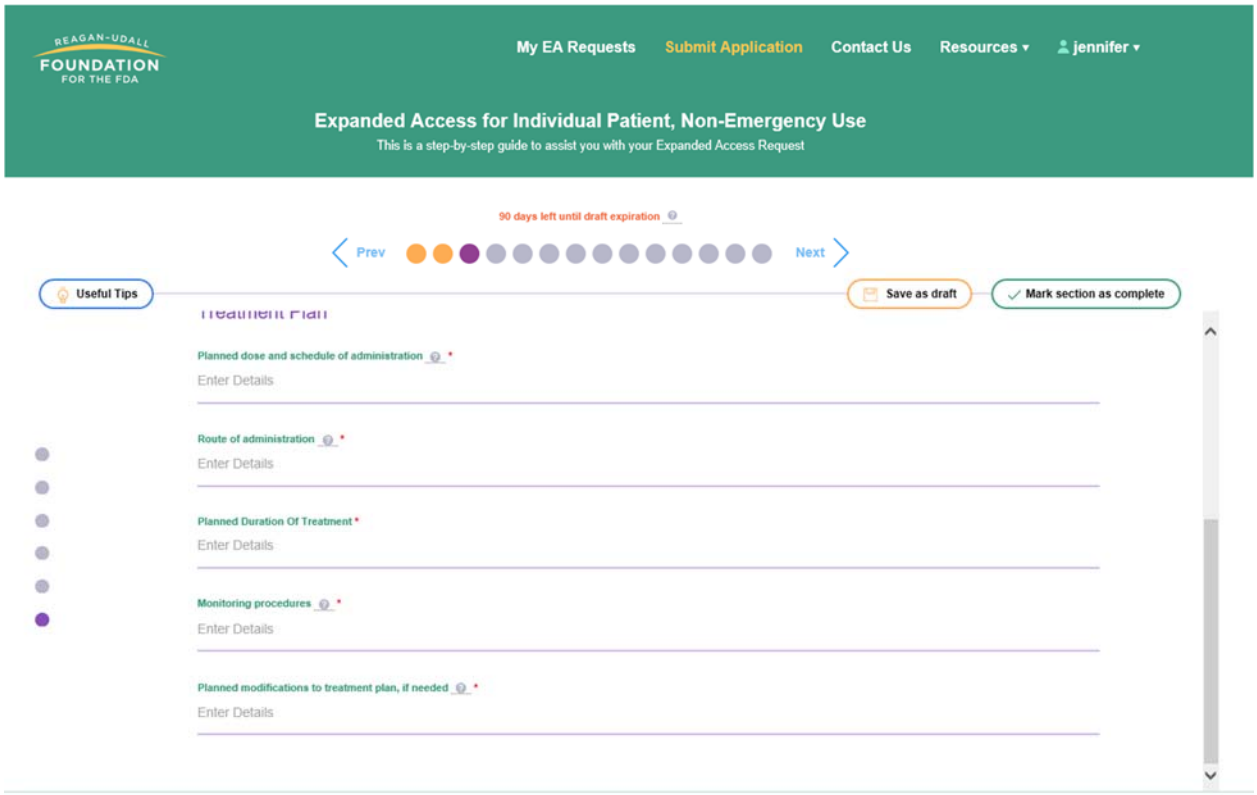
Mark section as complete
5. Treatment Information
Name of investigational drug/biological products being requested (100 Char) *
Enter Details
Name of the entity that will supply the drug/biological products (generally the manufacturer) (200 Char) *
Enter Details
FDA Review Division (if known) (200 Char)
Look Up a list of FDA Review Divisions
Enter Details
Treatment Plan
Planned dose and schedule of administration *
Enter Details
Route of administration *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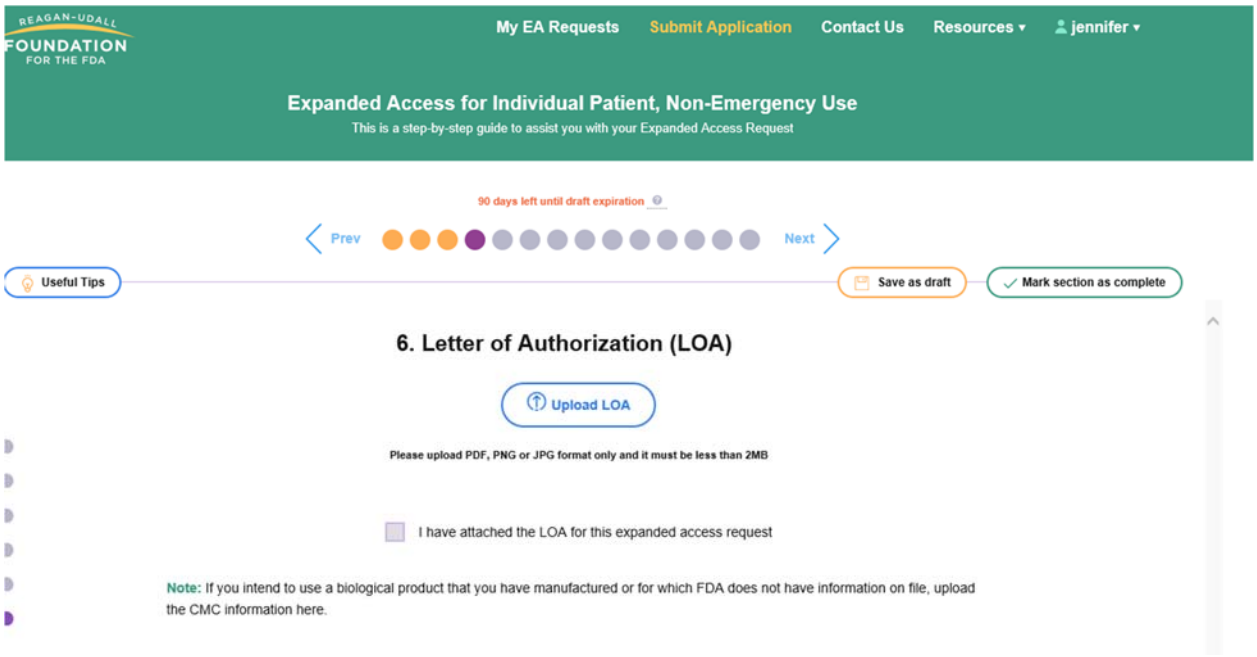
Mark section as complete
Planned dose and schedule of administration *
Enter Details
Route of administration *
Enter Details
Planned Duration Of Treatment *
Enter Details
Monitoring procedures *
Enter Details
Planned modifications to treatment plan, if needed *
Enter Details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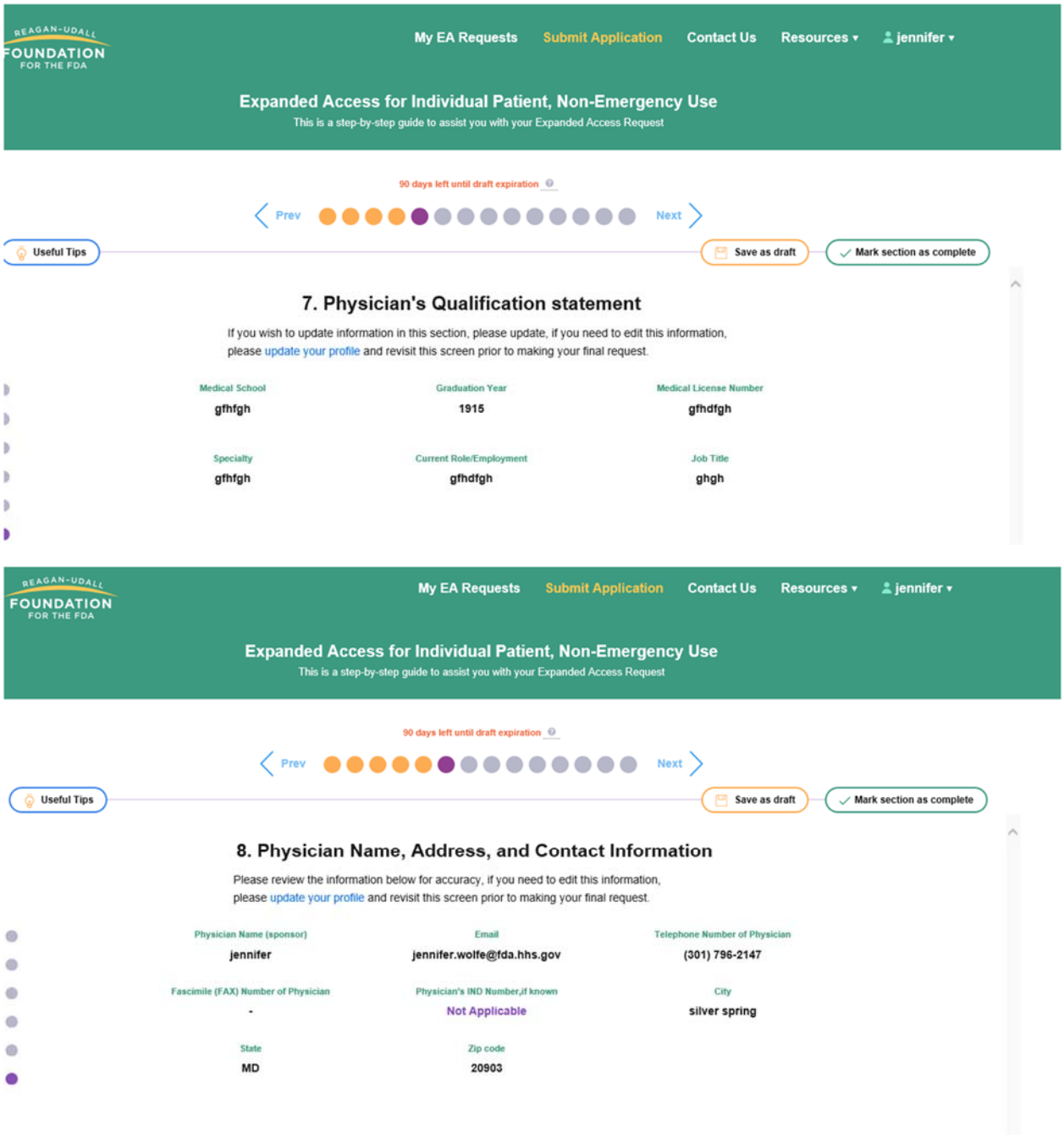
Mark section as complete
6. Letter of Authorization (LOA)
Upload LOA
Please upload PDF, PNG or JPG format only and it must be less than 2MB
I have attached the LOA for this expanded access request
Note: If you intend to use a biological product that you have manufactured or for which FDA does not have information on file, upload the CMC information here.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Mark section as complete
7. Physician's Qualification statement
If you wish to update information in this section, please update, if you need to edit this information, please update your profile and revisit this screen prior to making your final request.
Medical School
gfhfgh
Graduation Year
1915
Medical License Number
gfhdfgh
Specialty
gfhfgh
Current Role/Employment
gfhdfgh
Job Title
ghgh
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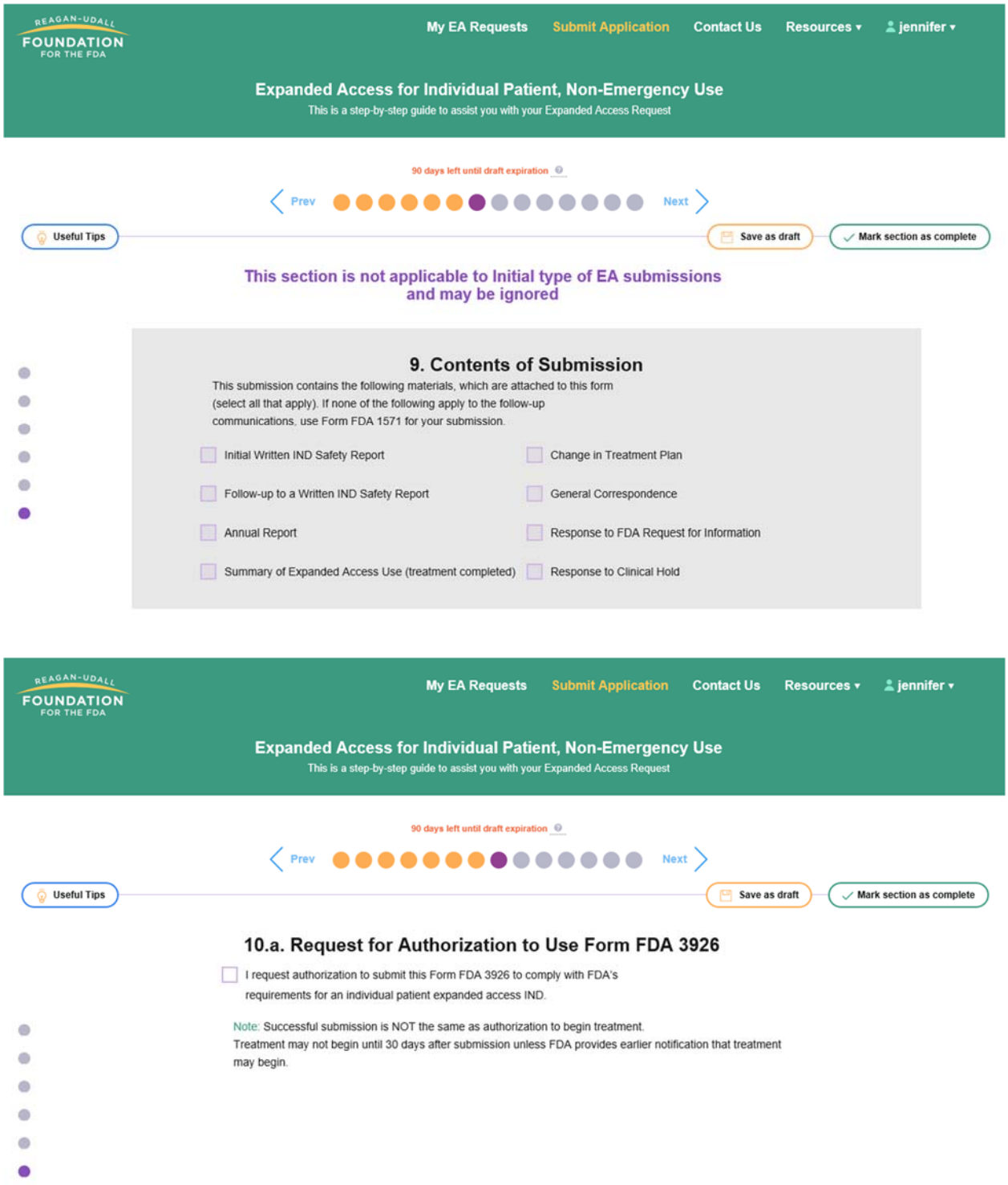
8. Physician Name, Address, and Contact Information
Please review the information below for accuracy, if you need to edit this information, please update your profile and revisit this screen prior to making your final request.
Physician Name (sponsor)
jennifer
Email
jennifer.wolfe@fda.hhs.gov
Telephone Number of Physician
(301) 796-2147
Fascimile (FAX) Number of Physician
-
Physician's IND Number,if known
Not Applicable
City
silver spring
State
MD
Zip code
20903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Mark section as complete
This section is not applicable to Initial type of EA submissions and may be ignored
9. Contents of Submission
This submission contains the following materials, which are attached to this form (select all that apply). If none of the following apply to the follow-up communications, use Form FDA 1571 for your submission.
Initial Written IND Safety Report
Follow-up to a Written IND Safety Report
Annual Report
Summary of Expanded Access Use (treatment completed)
Change in Treatment Plan
General Correspondence
Response to FDA Request for Information
Response to Clinical Hold
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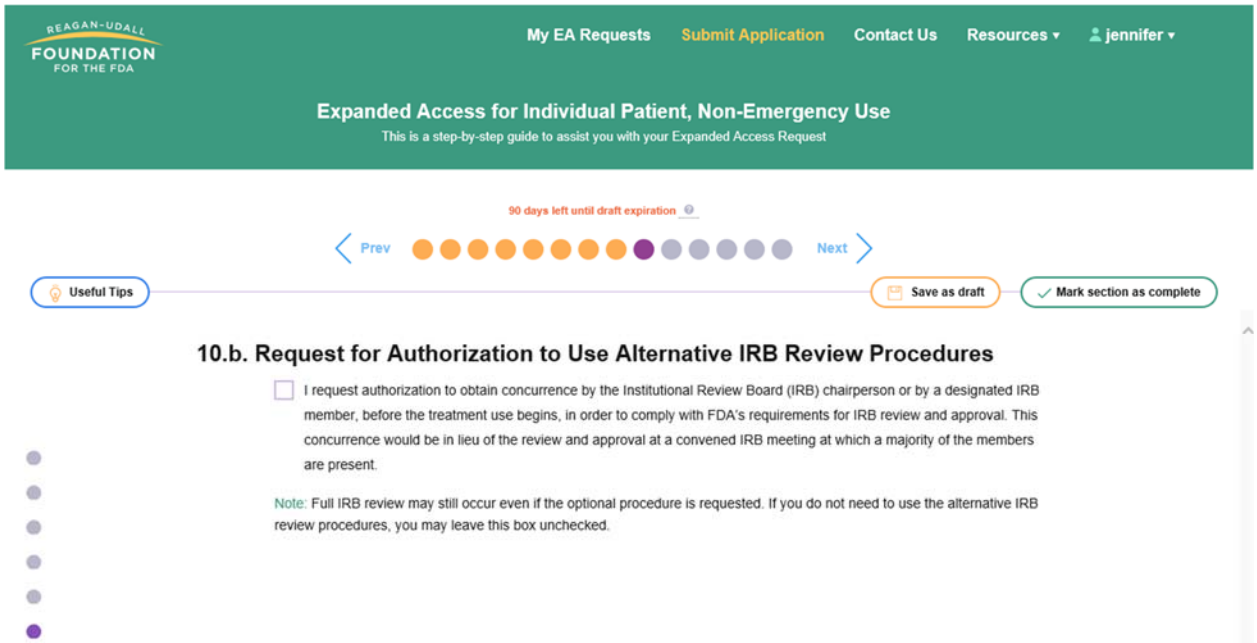
Mark section as complete
10.a. Request for Authorization to Use Form FDA 3926
I request authorization to submit this Form FDA 3926 to comply with FDA's requirements for an individual patient expanded access IND.
Note: Successful submission is NOT the same as authorization to begin treatment. Treatment may not begin until 30 days after submission unless FDA provides earlier notification that treatment may begin.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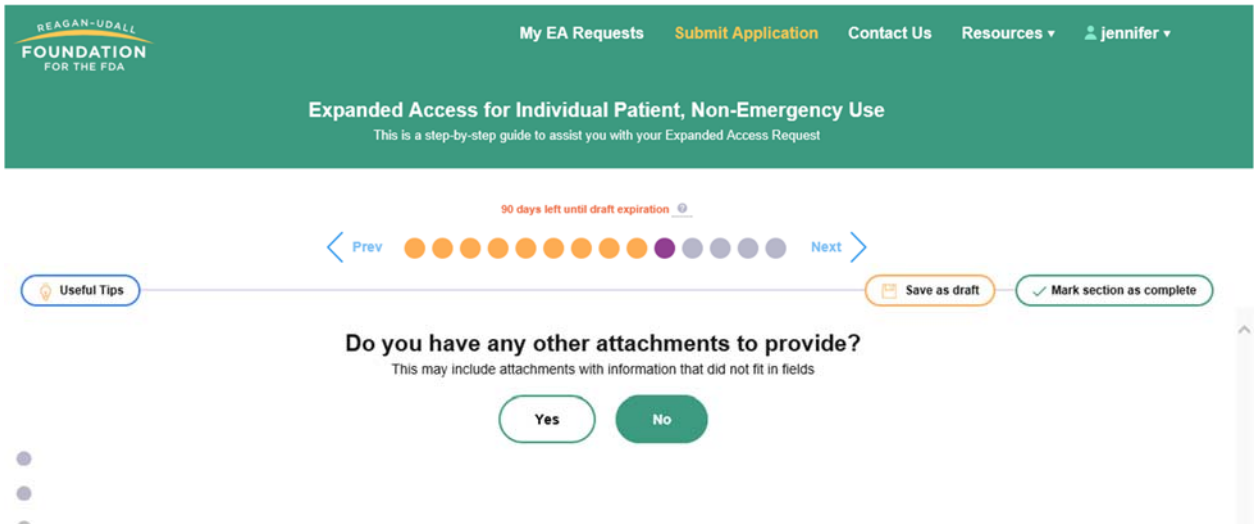
10.b. Request for Authorization to Use Alternative IRB Review Procedures
I request authorization to obtain concurrence by the Institutional Review Board (IRB) chairperson or by a designated IRB member, before the treatment use begins, in order to comply with FDA's requirements for IRB review and approval. This concurrence would be in lieu of the review and approval at a convened IRB meeting at which a majority of the members are present.
Note: Full IRB review may still occur even if the optional procedure is requested. If you do not need to use the alternative IRB review procedures, you may leave this box unchecked.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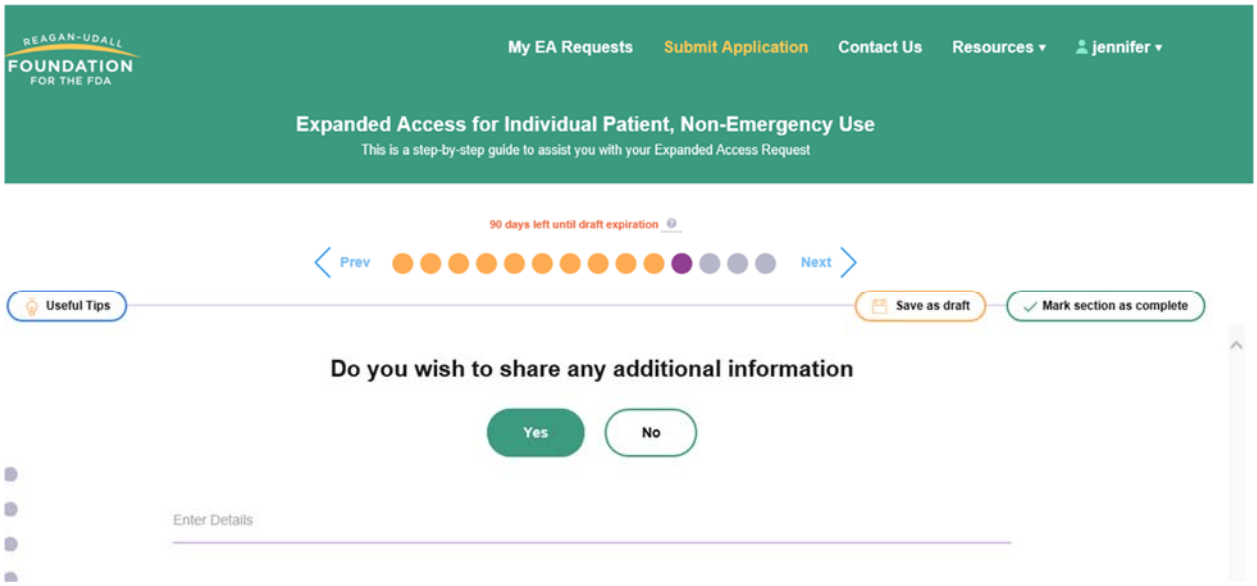
Do you have any other attachments to provide?
This may include attachments with information that did not fit in fields
Yes
No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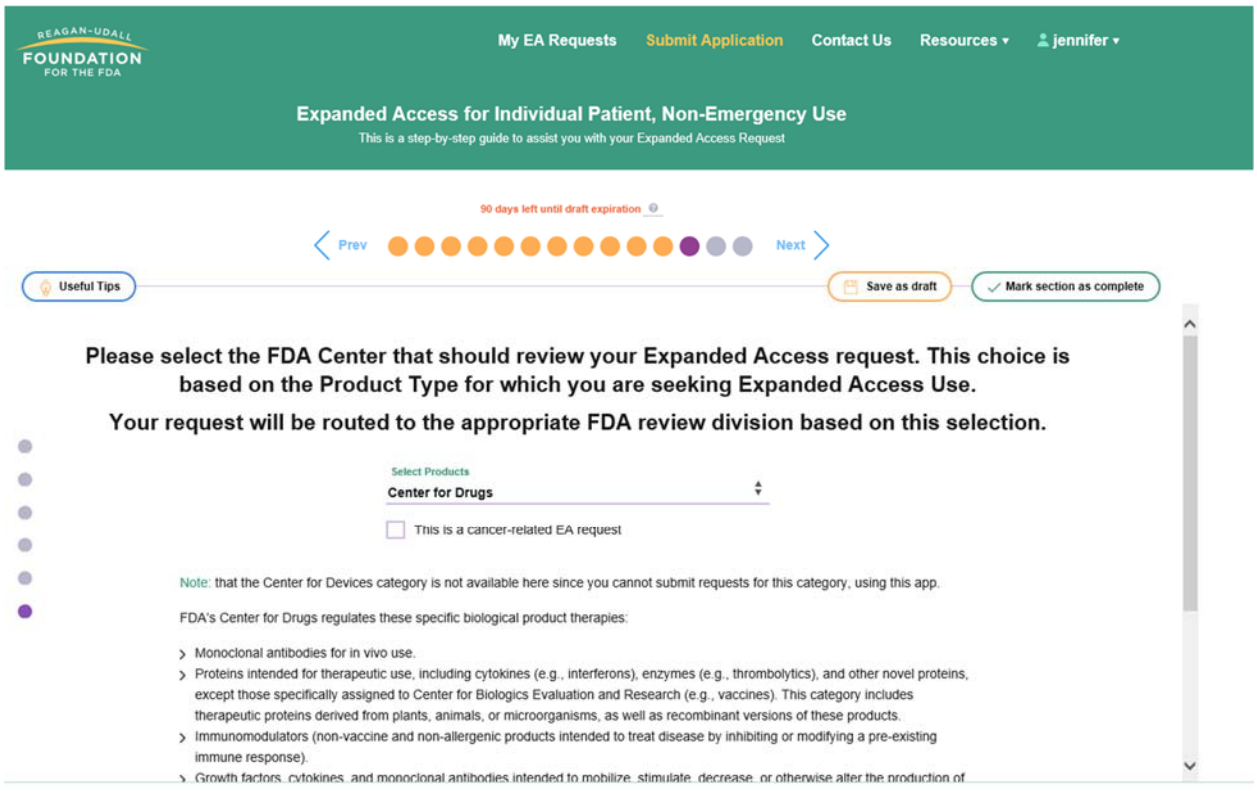
Do you wish to share any additional information
Yes
No
Enter Details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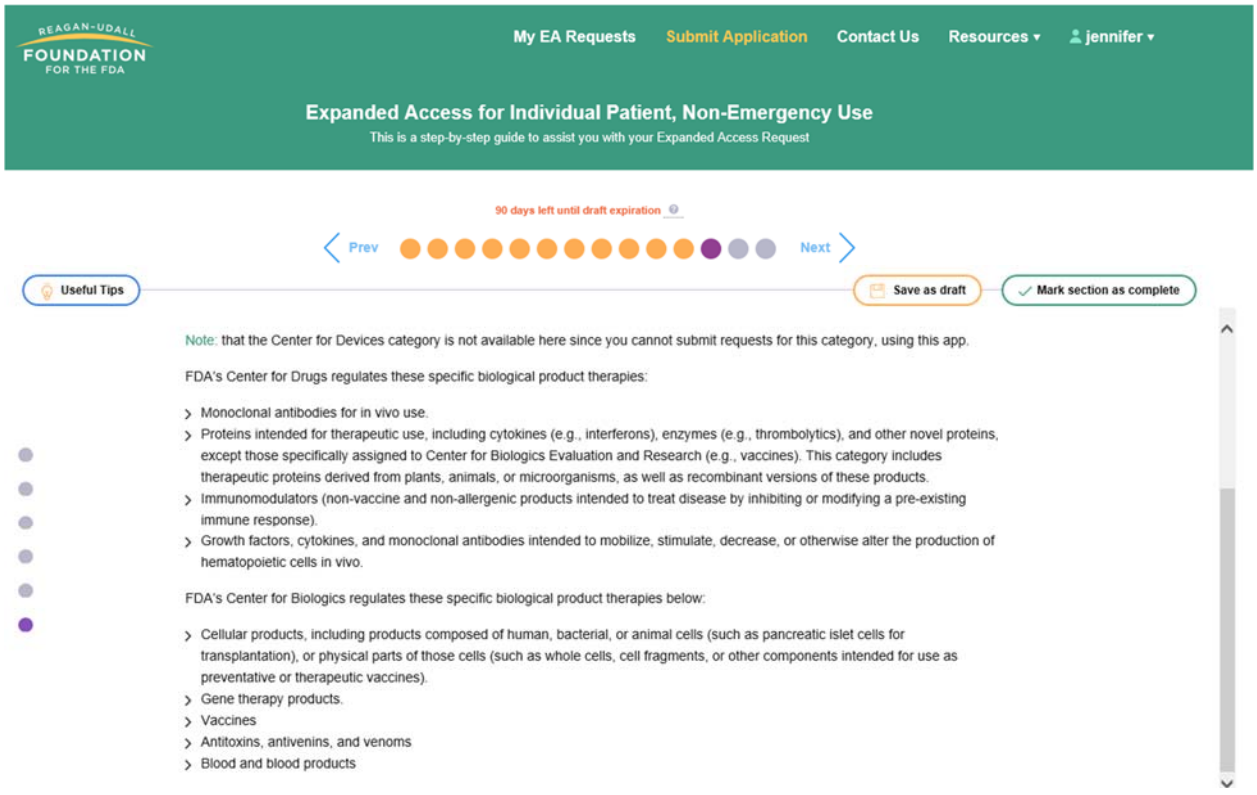
Mark section as complete
Please select the FDA Center that should review your Expanded Access request. This choice is based on the Product Type for which you are seeking Expanded Access Use.
Your request will be routed to the appropriate FDA review division based on this selection.
Select Products
Center for Drugs
This is a cancer-related EA request
Note: that the Center for Devices category is not available here since you cannot submit requests for this category, using this app.
FDA's Center for Drugs regulates these specific biological product therapies:
Monoclonal antibodies for in vivo use.
Proteins intended for therapeutic use, including cytokines (e.g., interferons), enzymes (e.g., thrombolytics), and other novel proteins, except those specifically assigned to Center for Biologics Evaluation and Research (e.g., vaccines). This category includes therapeutic proteins derived from plants, animals, or microorganisms, as well as recombinant versions of these products.
Immunomodulators (non-vaccine and non-allergenic products intended to treat disease by inhibiting or modifying a pre-existing immune response).
Growth factors, cytokines, and monoclonal antibodies intended to mobilize, stimulate, decrease, or otherwise alter the production of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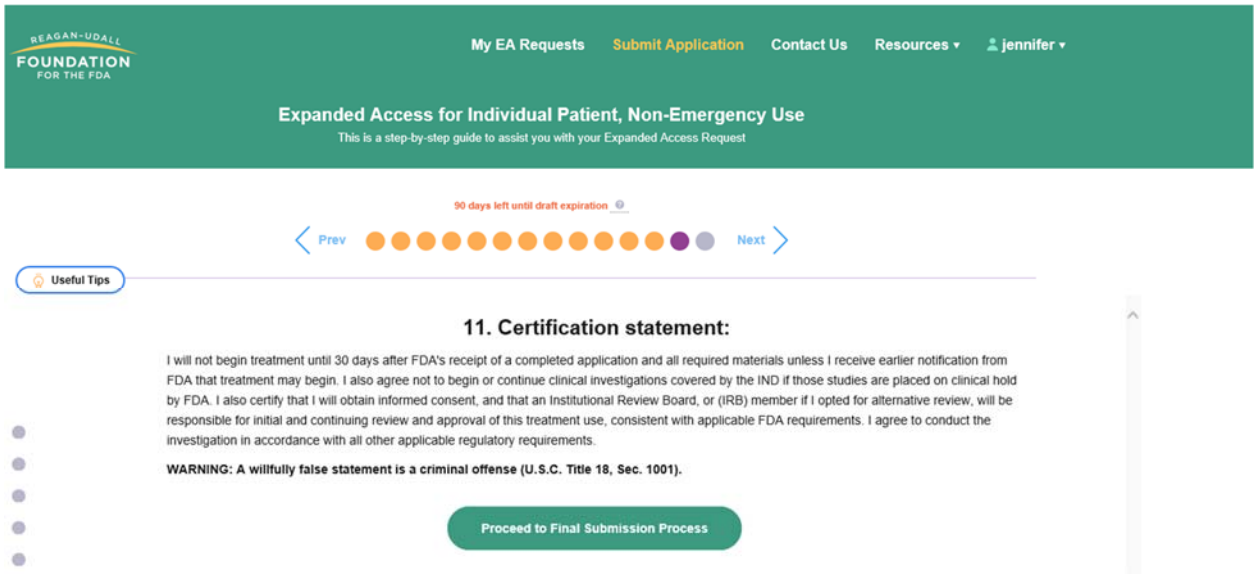
Note: that the Center for Devices category is not available here since you cannot submit requests for this category, using this app.
FDA's Center for Drugs regulates these specific biological product therapies:
Monoclonal antibodies for in vivo use.
Proteins intended for therapeutic use, including cytokines (e.g., interferons), enzymes (e.g., thrombolytics), and other novel proteins, except those specifically assigned to Center for Biologics Evaluation and Research (e.g., vaccines). This category includes therapeutic proteins derived from plants, animals, or microorganisms, as well as recombinant versions of these products.
Immunomodulators (non-vaccine and non-allergenic products intended to treat disease by inhibiting or modifying a pre-existing immune response).
Growth factors, cytokines, and monoclonal antibodies intended to mobilize, stimulate, decrease, or otherwise alter the production of hematopoietic cells in vivo.
FDA's Center for Biologics regulates these specific biological product therapies below:
Cellular products, including products composed of human, bacterial, or animal cells (such as pancreatic islet cells for transplantation), or physical parts of those cells (such as whole cells, cell fragments, or other components intended for use as preventative or therapeutic vaccines).
Gene therapy products.
Vaccines
Antitoxins, antivenins, and venoms
Blood and blood products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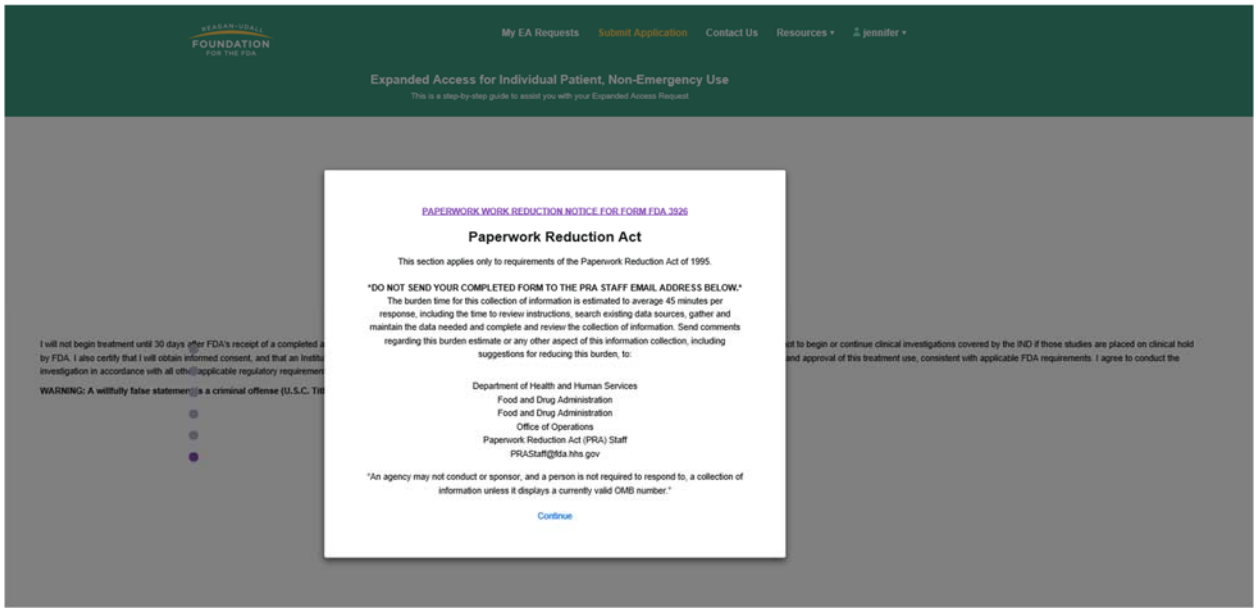
11. Certification statement:
I will not begin treatment until 30 days after FDA's receipt of a completed application and all required materials unless I receive earlier notification from FDA that treatment may begin. I also agree not to begin or continue clinical investigations covered by the IND if those studies are placed on clinical hold by FDA. I also certify that I will obtain informed consent, and that an Institutional Review Board, or (IRB) member if I opted for alternative review, will be responsible for initial and continuing review and approval of this treatment use, consistent with applicable FDA requirements. I agree to conduct the investigation in accordance with all other applicable regulatory requirements.
WARNING: A willfully false statement is a criminal offense (U.S.C. Title 18, Sec. 1001).
Proceed to Final Submission Process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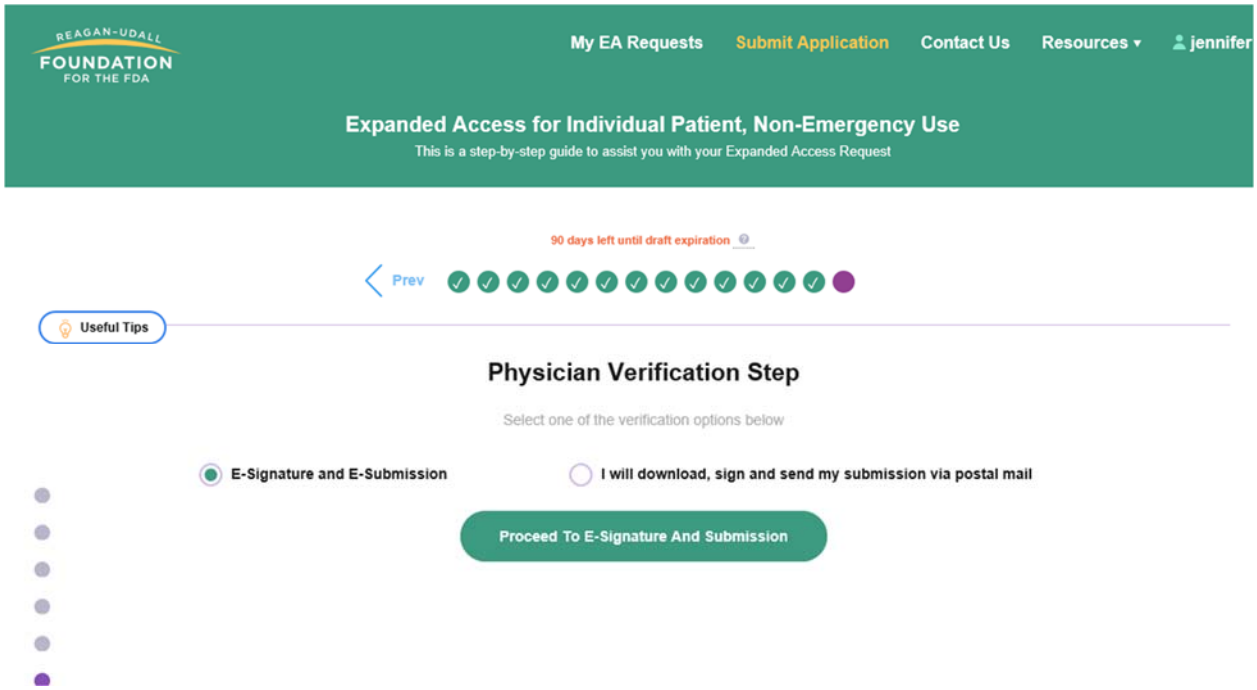
PAPERWORK WORK REDUCTION NOTICE FOR FORM FDA 3926
Paperwork Reduction Act
This section applies only to requirements of the Paperwork Reduction Act of 1995.
DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.
The burden time for this collection of information is estimated to average 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
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."
Continue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Physician Verification Step
Select one of the verification options below
E-Signature and E-Submission
I will download, sign and send my submission via postal mail
Proceed To E-Signature And Submission