

**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)

<b>APPLICANT INFORMATION</b>	2. Name of Applicant
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3. Telephone Number (Include country code if applicable and area code)	4. Facsimile (FAX) Number (Include country code if applicable and area code)
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5. Applicant Address				Email Address
Address 1 (Street address, P.O. box, company name c/o)		State/Province/Region		
Address 2 (Apartment, suite, unit, building, floor, etc.)		City		U.S. License Number if previously issued
Country		ZIP or Postal Code		

6. Authorized U.S. Agent (Required for non-U.S. applicants)				Telephone Number (Include area code)
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		FAX Number (Include area code)
State		ZIP Code		
				Email Address

<b>PRODUCT DESCRIPTION</b>	7. NDA, ANDA, or BLA Application Number	8. Supplement Number (If applicable)
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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
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15. Proposed Indication for Use	Is this indication for a rare disease (prevalence <200,000 in U.S.)? <input type="checkbox"/> Yes <input type="checkbox"/> No	
	Does this product have an FDA Orphan Designation for this indication? <input type="checkbox"/> Yes <input type="checkbox"/> No	If yes, provide the Orphan Designation number for this indication: <input type="text"/>

**Contin. Page for #15**

<b>APPLICATION INFORMATION</b>	16. Application Type (Select one)	<input type="checkbox"/> New Drug Application (NDA)	<input type="checkbox"/> Biologics License Application (BLA)
		<input type="checkbox"/> Abbreviated New Drug Application (ANDA)	

17. If an NDA, identify the type <input type="checkbox"/> 505(b)(1) <input type="checkbox"/> 505(b)(2)	18. If a BLA, identify the type <input type="checkbox"/> 351(a) <input type="checkbox"/> 351(k)
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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(s) that is/are the basis for the submission.  
 Name of Drug(s): \_\_\_\_\_ Application Number(s) of Relied Upon Product(s): \_\_\_\_\_

Indicate Patent Certification(s):  P1  P2  P3  P4  Section viii - MOU  Statement of no relevant patents

21. Submission (See instructions)  Original  Labeling Supplement  CMC Supplement  Efficacy Supplement  Annual Report  
 Product Correspondence  REMS Supplement  Postmarketing Requirements or Commitments  Periodic Safety Report  
 Request for Proprietary Name Review  Other (Specify): \_\_\_\_\_

22. Submission Sub-Type <input type="checkbox"/> Presubmission <input type="checkbox"/> Amendment <input type="checkbox"/> Initial Submission <input type="checkbox"/> Resubmission	23. If a supplement, identify the appropriate category. <input type="checkbox"/> CBE <input type="checkbox"/> Prior Approval (PA) <input type="checkbox"/> CBE-30
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24. Does this submission contain:  
 Only Pediatric data?  Yes     No    Human Factors information?  Yes     No

25. Reasons for Submission

26. Proposed Marketing Status (*Select one*)  
 Prescription Product (Rx)     Over-The-Counter Product (OTC)

27. Establishment Information (*Full establishment information should be provided in the body of the application.*)  
*Refer to the instruction sheet (Form FDA 356h Supplement) for more information.*

Establishment Name	
Address 1 ( <i>Street address, P.O. box, company name c/o</i> )	Registration (FEI) Number
Address 2 ( <i>Apartment, suite, unit, building, floor, etc.</i> )	MF Number
City	State/Province/Region
Country	ZIP or Postal Code
Establishment DUNS Number	
Is the establishment new to the application? <input type="checkbox"/> Yes <input type="checkbox"/> No	What is the status of the establishment? <input type="checkbox"/> Pending <input type="checkbox"/> Active <input type="checkbox"/> Inactive <input type="checkbox"/> Withdrawn

*Establishment Contact Information at the site/facility*

Name of Contact for the Establishment	Telephone Number ( <i>Include area code</i> )
Address 1 ( <i>Street address, P.O. box, company name c/o</i> )	FAX Number ( <i>Include area code</i> )
Address 2 ( <i>Apartment, suite, unit, building, floor, etc.</i> )	Email Address
City	State/Province/Region
Country	ZIP or Postal Code

Manufacturing Steps and/or Type of Testing	Is the site ready for inspection? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A If No, when will site be ready? ( <i>mm/dd/yyyy</i> ) _____
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Continuation Page for #27

28. Cross References (List related BLAs, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, MAFs, and DMFs referenced in the current application.)

Contin. Page for #28

29. This application contains the following items (*Select all that apply*)

<input type="checkbox"/> 1. Index	<input type="checkbox"/> 2. Labeling ( <i>Select one</i> ): <input type="checkbox"/> Draft Labeling <input type="checkbox"/> Final Printed Labeling	<input type="checkbox"/> 3. Summary ( <i>21 CFR 314.50 (c)</i> )
<input type="checkbox"/> 4. Chemistry Section <input type="checkbox"/> A. Chemistry, manufacturing, and controls information ( <i>e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2</i> ) <input type="checkbox"/> B. Samples ( <i>21 CFR 314.50 (e)(1); 21 CFR 601.2 (a)</i> ) ( <i>Submit only upon FDA's request</i> ) <input type="checkbox"/> C. Methods validation package ( <i>e.g., 21 CFR 314.50(e)(2)(i); 21 CFR 601.2</i> )		
<input type="checkbox"/> 5. Nonclinical pharmacology and toxicology section ( <i>e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2</i> )	<input type="checkbox"/> 6. Human pharmacokinetics and bioavailability section ( <i>e.g., 21 CFR 314.50(d)(3); 21 CFR 601.2</i> )	
<input type="checkbox"/> 7. Clinical microbiology section ( <i>e.g., 21 CFR 314.50(d)(4)</i> )	<input type="checkbox"/> 8. Clinical data section ( <i>e.g., 21 CFR 314.50(d)(5); 21 CFR 601.2</i> )	

*Item 29 continued on page 3*

29. This application contains the following items (Continued; select all that apply)

<input type="checkbox"/> 9. Safety update report (e.g., 21 CFR 314.50(d)(5)(vi)(b); 21 CFR 601.2)	<input type="checkbox"/> 10. Statistical section (e.g., 21 CFR 314.50(d)(6); 21 CFR 601.2)
<input type="checkbox"/> 11. Case report tabulations (e.g., 21 CFR 314.50(f)(1); 21 CFR 601.2)	<input type="checkbox"/> 12. Case report forms (e.g., 21 CFR 314.50 (f)(2); 21 CFR 601.2)
<input type="checkbox"/> 13. Patent information on any patent that claims the drug/biologic (21 U.S.C. 355(b) or (c))	<input type="checkbox"/> 14. A patent certification with respect to any patent that claims the drug/biologic (21 U.S.C. 355 (b)(2) or (j)(2)(A))
<input type="checkbox"/> 15. Establishment description (21 CFR Part 600, if applicable)	<input type="checkbox"/> 16. Debarment certification (FD&C Act 306 (k)(1))
<input type="checkbox"/> 17. Field copy certification (21 CFR 314.50 (l)(3))	<input type="checkbox"/> 18. User Fee Cover Sheet (PDUFA Form FDA 3397, GDUFA Form FDA 3794, BsUFA Form FDA 3792, or MDUFA Form FDA 3601)
<input type="checkbox"/> 19. Financial Disclosure Information (21 CFR Part 54)	
<input type="checkbox"/> 20. Other (Specify): _____	

**CERTIFICATION**

I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to, the following:

1. Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR Part 202.
5. Regulations on making changes in application in FD&C Act section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80, and 600.81.
7. Local, state, and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been reviewed and, to the best of my knowledge, are certified to be true and accurate.

**Warning:** A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

30. Typed Name and Title of Applicant's Responsible Official	31. Date (mm/dd/yyyy)
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32. Telephone Number (Include country code if applicable and area code)	33. FAX Number (Include country code if applicable and area code)	34. Email Address
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35. Address of Applicant's Responsible Official	
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

36. Signature of Applicant's Responsible Official or Other Authorized Official	<b>Sign</b>	37. Countersignature of Authorized U.S. Agent	<b>Sign</b>
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**The information below applies only to requirements of the Paperwork Reduction Act of 1995.**

The burden time for this collection of information is estimated to average 24 hours 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 the address to the right:

Department of Health and Human Services  
 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."

**DO NOT SEND YOUR COMPLETED FORM TO THIS PRA STAFF EMAIL ADDRESS.**

**FIRST CONTINUATION PAGE FOR ITEM 15 – Proposed Indication for Use**

Please fill out as many sets of answers as needed, completing all elements within each set that you start.

Proposed Indication for Use	Is this indication for a rare disease (prevalence <200,000 in U.S.)? <input type="checkbox"/> Yes <input type="checkbox"/> No	
	Does this product have an FDA Orphan Designation for this indication? <input type="checkbox"/> Yes <input type="checkbox"/> No	If yes, provide the Orphan Designation number for this indication: <input type="text"/>
Proposed Indication for Use	Is this indication for a rare disease (prevalence <200,000 in U.S.)? <input type="checkbox"/> Yes <input type="checkbox"/> No	
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Proposed Indication for Use	Is this indication for a rare disease (prevalence <200,000 in U.S.)? <input type="checkbox"/> Yes <input type="checkbox"/> No	
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Proposed Indication for Use	Is this indication for a rare disease (prevalence <200,000 in U.S.)? <input type="checkbox"/> Yes <input type="checkbox"/> No	
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Proposed Indication for Use	Is this indication for a rare disease (prevalence <200,000 in U.S.)? <input type="checkbox"/> Yes <input type="checkbox"/> No	
	Does this product have an FDA Orphan Designation for this indication? <input type="checkbox"/> Yes <input type="checkbox"/> No	If yes, provide the Orphan Designation number for this indication: <input type="text"/>
Proposed Indication for Use	Is this indication for a rare disease (prevalence <200,000 in U.S.)? <input type="checkbox"/> Yes <input type="checkbox"/> No	
	Does this product have an FDA Orphan Designation for this indication? <input type="checkbox"/> Yes <input type="checkbox"/> No	If yes, provide the Orphan Designation number for this indication: <input type="text"/>
Proposed Indication for Use	Is this indication for a rare disease (prevalence <200,000 in U.S.)? <input type="checkbox"/> Yes <input type="checkbox"/> No	
	Does this product have an FDA Orphan Designation for this indication? <input type="checkbox"/> Yes <input type="checkbox"/> No	If yes, provide the Orphan Designation number for this indication: <input type="text"/>
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	Does this product have an FDA Orphan Designation for this indication? <input type="checkbox"/> Yes <input type="checkbox"/> No	If yes, provide the Orphan Designation number for this indication: <input type="text"/>
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	Does this product have an FDA Orphan Designation for this indication? <input type="checkbox"/> Yes <input type="checkbox"/> No	If yes, provide the Orphan Designation number for this indication: <input type="text"/>
Proposed Indication for Use	Is this indication for a rare disease (prevalence <200,000 in U.S.)? <input type="checkbox"/> Yes <input type="checkbox"/> No	
	Does this product have an FDA Orphan Designation for this indication? <input type="checkbox"/> Yes <input type="checkbox"/> No	If yes, provide the Orphan Designation number for this indication: <input type="text"/>

## FIRST CONTINUATION PAGE FOR ITEM 27 – Establishment Information

Provide information for additional establishments below, as needed.

Establishment Name

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

Registration (FEI) Number

MF Number

Establishment DUNS Number

Is the establishment new to the application?

 Yes  No

What is the status of the establishment?

 Pending  Active  Inactive  Withdrawn**Establishment Contact Information**

Name of Contact for the Establishment

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

Telephone Number (Include area code)

FAX Number (Include area code)

Email Address

Manufacturing Steps and/or Type of Testing

Is the site ready for inspection?  Yes  No  N/A

If No, when will site be ready? (mm/dd/yyyy) \_\_\_\_\_

Establishment Name

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

Registration (FEI) Number

MF Number

Establishment DUNS Number

Is the establishment new to the application?

 Yes  No

What is the status of the establishment?

 Pending  Active  Inactive  Withdrawn**Establishment Contact Information**

Name of Contact for the Establishment

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

Telephone Number (Include area code)

FAX Number (Include area code)

Email Address

Manufacturing Steps and/or Type of Testing

Is the site ready for inspection?  Yes  No  N/A

If No, when will site be ready? (mm/dd/yyyy) \_\_\_\_\_

Add Second Continuation Page for #27