

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: December 31, 2017

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)

Email Address

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

City

State/Province/Region

U.S. License Number if previously issued

Country

ZIP or Postal Code

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

Authorized U.S. Agent Name

Telephone Number (Include area code)

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

FAX Number (Include area code)

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

City

State

Email Address

ZIP Code

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

15. Proposed Indication for Use

Is this indication for a rare disease (prevalence <200,000 in U.S.)? ☐ Yes ☐ NoDoes this product have an FDA Orphan Designation for this indication? ☐ Yes ☐ NoIf yes, provide the Orphan Designation number for this indication: Contin.
Page for
#15

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 the basis for the submission.

Name of Drug: _____ Application Number of Relied Upon Product: _____

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☐ Other (Specify): _____

22. Submission Sub-Type ☐ Presubmission ☐ Amendment ☐ Initial Submission ☐ Resubmission	23. If a supplement, identify the appropriate category. ☐ CBE ☐ Prior Approval (PA) ☐ CBE-30																								
24. Does this submission contain <i>only</i> pediatric data? ☐ Yes ☐ No																									
25. Reasons for Submission																									
26. Proposed Marketing Status (<i>Select one</i>) ☐ Prescription Product (Rx) ☐ Over-The-Counter Product (OTC)																									
27. This application is (<i>Select one</i>) ☐ Paper ☐ Paper and Electronic ☐ Electronic	28. Number of Volumes Submitted																								
29. Establishment Information (<i>Full establishment information should be provided in the body of the application.</i>) <i>Refer to the instruction sheet (Form FDA 356h Supplement) for more information.</i>																									
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30. Cross References (List related BLAs, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, MAFs, and DMFs referenced in the current application.) Contin. Page for #30																									
31. This application contains the following items (<i>Select all that apply</i>)																									
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Item 31 continued on page 3

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

- | | |
|---|--|
| ☐ 9. Safety update report (e.g., 21 CFR 314.50(d)(5)(vi)(b); 21 CFR 601.2) | ☐ 10. Statistical section (e.g., 21 CFR 314.50(d)(6); 21 CFR 601.2) |
| ☐ 11. Case report tabulations (e.g., 21 CFR 314.50(f)(1); 21 CFR 601.2) | ☐ 12. Case report forms (e.g., 21 CFR 314.50 (f)(2); 21 CFR 601.2) |
| ☐ 13. Patent information on any patent that claims the drug/biologic (21 U.S.C. 355(b) or (c)) | ☐ 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)) |
| ☐ 15. Establishment description (21 CFR Part 600, if applicable) | ☐ 16. Debarment certification (FD&C Act 306 (k)(1)) |
| ☐ 17. Field copy certification (21 CFR 314.50 (l)(3)) | ☐ 18. User Fee Cover Sheet (PDUFA Form FDA 3397, GDUFA Form FDA 3794, BsUFA Form FDA 3792, or MDUFMA Form FDA 3601) |
| ☐ 19. Financial Disclosure Information (21 CFR Part 54) | |
| ☐ 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.

32. Typed Name and Title of Applicant's Responsible Official			33. Date (mm/dd/yyyy)	
34. Telephone Number (Include country code if applicable and area code)	35. FAX Number (Include country code if applicable and area code)	36. Email Address		
37. 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		
38. Signature of Applicant's Responsible Official or Other Authorized Official		39. Countersignature of Authorized U.S. Agent		
Sign		Sign		

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 Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@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.