

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)

Email Address

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

Applicant DUNS

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.)

Email Address

City

State

U.S. Agent DUNS

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

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

| | | | |
|---|---|--|---|
| 21. Submission (<i>See instructions</i>) <input type="checkbox"/> Original <input type="checkbox"/> Labeling Supplement <input type="checkbox"/> CMC Supplement <input type="checkbox"/> Efficacy Supplement <input type="checkbox"/> Annual Report <input type="checkbox"/> Product Correspondence <input type="checkbox"/> REMS Supplement <input type="checkbox"/> Postmarketing Requirements or Commitments <input type="checkbox"/> Periodic Safety Report <input type="checkbox"/> Request for Proprietary Name Review <input type="checkbox"/> Other (<i>Specify</i>): _____ | | | |
| 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 | |
| 24. For Originals and all Supplements, is the product a combination product (21 CFR 3.2(e))? <input type="checkbox"/> Yes <input type="checkbox"/> No | | Combination Product Type (<i>See instructions</i>) | Request for Designation (RFD) Number |
| 25. Does the submission contain: Only Pediatric data? <input type="checkbox"/> Yes <input type="checkbox"/> No | | Human factors information? <input type="checkbox"/> Yes <input type="checkbox"/> No | 26. Proposed Marketing Status (<i>Select one</i>) <input type="checkbox"/> Prescription Product (Rx) <input type="checkbox"/> Over-The-Counter Product (OTC) |
| 27. Reasons for Submission | | | |
| 28. Establishment Information (<i>Full establishment information should be provided in the body of the application.</i>) | | | |
| 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>) | | | |
| City | State/Province/Region | MF Number | |
| 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>) | | | |
| City | State/Province/Region | Email Address | |
| 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>) _____ | |
| | | Continuation Page for #28 | |
| 29. Cross References (List related BLAs, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, MAFs, and DMFs referenced in the current application.) | | | |
| <div style="border: 1px solid black; padding: 2px; display: inline-block;"> Contin. Page for #29 </div> | | | |
| 30. This application contains the following items (<i>Select all that apply</i>) | | | |
| <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 30 continued on page 3

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

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|---|--|
| <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.

| | | | | | |
|--|--|---|---|-------------------|--|
| 31. Typed Name and Title of Applicant's Responsible Official | | | 32. Date (mm/dd/yyyy) | | |
| 33. Telephone Number (Include country code if applicable and area code) | | 34. FAX Number (Include country code if applicable and area code) | | 35. Email Address | |
| 36. 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 | | |
| 37. Signature of Applicant's Responsible Official or Other Authorized Official | | | 38. Countersignature of Authorized U.S. Agent | | |
| Sign | | | Sign | | |

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Food and Drug Administration
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PRASStaff@fda.hhs.gov

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