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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, 2026
See PRA Statement on page 4

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)*

U.S. Agent Company | Prefix | First Name | Middle | Last Name | Title

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

Telephone Number *(Include area code)*

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

U.S. Agent DUNS

FAX Number *(Include area code)*

City | State | ZIP Code | Email Address

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:

15B. SNOMED CT Indication Disease Term *(Use continuation page for each additional indication and respective coded disease term)*

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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 *(See instructions)*

☐ Original ☐ Labeling Supplement ☐ CMC Supplement

☐ Efficacy Supplement ☐ Annual Report ☐ Product Correspondence

☐ Postmarketing Requirements or Commitments ☐ Request for Proprietary Name Review ☐ Periodic Safety Report

☐ REMS Supplement ☐ REMS Assessment Report

☐ REMS Assessment Methods and Study Protocols

☐ Human Factors *(Specify Type)*:

☐ 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. For Originals and all Supplements, is the product a combination product *(21 CFR 3.2(e))?*

☐ Yes ☐ No

Combination Product Type *(See instructions)*

Request for Designation (RFD) Number

25. Does the submission contain:

Only Pediatric data? ☐ Yes ☐ No

Digital Health Technology (DHT) data? ☐ Yes ☐ No

26. Proposed Marketing Status *(Select one)*

☐ Prescription Product (Rx)

☐ Over-The-Counter Product (OTC)

27. Reasons for Submission

28. Establishment Information *(Full establishment information should be provided in the body of the application.)*

Establishment Name			Registration (FEI) Number
Address 1 *(Street address, P.O. box, company name c/o)*			MF Number
Address 2 *(Apartment, suite, unit, building, floor, etc.)*			Establishment DUNS Number
City	State/Province/Region	ZIP or Postal Code	Country

Is the establishment new to the application?	Is this establishment involved in the change described in this supplement?	What is the status of the establishment?
☐ Yes ☐ No	☐ Yes ☐ No	☐ Pending ☐ Active ☐ Inactive ☐ Withdrawn

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Establishment Contact Information at the site/facility

Prefix	First Name	Middle	Last Name	Title

Address 1 *(Street address, P.O. box, company name c/o)*	Telephone Number *(Include area code)*
Address 2 *(Apartment, suite, unit, building, floor, etc.)*	FAX Number *(Include area code)*
City / State/Province/Region	Email Address
Country	ZIP or Postal Code

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)*

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29. Cross References *(List related BLAs, INDs, NDAs, PMAs, 510(k)s, IDEs, MFs and DMFs referenced in the current application.)*

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

1. ☐ Index
2. ☐ Labeling (Select one):
   - ☐ Draft Labeling
   - ☐ Final Printed Labeling
3. ☐ Summary (21 CFR 314.50 (c))
4. ☐ Chemistry Section
   - A. ☐ Chemistry, manufacturing, and controls information (e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2)
   - B. ☐ Samples (21 CFR 314.50 (e)(1); 21 CFR 601.2 (a)) (Submit only upon FDA's request)
   - C. ☐ Methods validation package (e.g., 21 CFR 314.50(e)(2)(i); 21 CFR 601.2)
5. ☐ Nonclinical pharmacology and toxicology section (e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2)
6. ☐ Human pharmacokinetics and bioavailability section (e.g., 21 CFR 314.50(d)(3); 21 CFR 601.2)
7. ☐ Clinical microbiology section (e.g., 21 CFR 314.50(d)(4))
8. ☐ Clinical data section (e.g., 21 CFR 314.50(d)(5); 21 CFR 601.2)
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 MDUFA Form FDA 3601)
19. ☐ Financial Disclosure Information (21 CFR Part 54)
20. ☐ Other (Specify):

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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. Applicant's Responsible Official

Prefix	First Name	Middle	Last Name	Title

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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