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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: 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)*

(FAX) Number *(Include country code if applicable and area code)*

5. Applicant Address

Address 1 *(Street address, , company name c/o)*

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

City State/Province/Region

Country ZIP or Postal Code

Email Address

6. Authorized Agent *(Required for)*

Authorized

Address 1 *(Street address, , company name c/o)*

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

City State

ZIP Code

Telephone Number *(Include area code)*

FAX Number *(Include area code)*

Email Address

PRODUCT DESCRIPTION

7. NDA, ANDA, or BLA Application Number

8. Supplement Number *(If applicable)*

9. Established Name *(, 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

Is this indication for a rare disease (prevalence <200,000 in)? 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:

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APPLICATION INFORMATION

16. Application Type *(Select one)*

New Drug Application (NDA) ☐ Biologics License Application (BLA) ☐

Abbreviated New Drug Application (ANDA)

, identify the type, identify the type ☐ 505(b)(1) 505(b)(2) 351(a) 351(k) ☐ ☐

(k), identify the biological reference product that is the basis for the submission.

Name of Biologic: Holder of Licensed Application:

, 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 - MDU 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)*:

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