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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: January 31, 2017
See PRA Statement on page 3.

1. Date of Submission *(mm/dd/yyyy)*: 08/25/2014

APPLICANT INFORMATION

2. Name of Applicant: Mallinckrodt Inc.

3. Telephone Number *(Include country code if applicable and area code)*: 314-654-2000

4. Facsimile (FAX) Number *(Include country code if applicable and area code)*: 314-654-6496

5. Applicant Address

Address 1 *(Street address, P.O. box, company name c/o)*: 675 McDonnell Boulevard

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

City: Hazelwood

State/Province/Region: MO

Country: USA

ZIP or Postal Code: 63042

Email Address: RA.Generics@mallinckrodt.com

U.S. License Number if previously issued:

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

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:

State:

ZIP Code:

Telephone Number *(Include area code)*:

FAX Number *(Include area code)*:

Email Address:

PRODUCT DESCRIPTION

7. NDA, ANDA, or BLA Application Number: 021011

8. Supplement Number *(If applicable)*:

9. Established Name *(e.g., proper name, USP/USAN name)*: Oxycodone Hydrochloride Tablets USP

10. Proprietary Name *(Trade Name) (If any)*: Roxicodone

11. Chemical/Biochemical/Blood Product Name *(If any)*: 4, 5α-epoxy-14-hydroxy-3-methoxy-17-methylmorphinan-6-one hydrochloride

12. Dosage Form: Tablets

13. Strengths: 5 mg, 15 mg, and 30 mg

14. Route of Administration: Oral

15. Proposed Indication for Use: for the management of moderate to severe pain where the use of an opioid analgesic is appropriate

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:

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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 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 *(Select one)*: ☐ 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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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 *only* pediatric data? ☐ Yes ☐ No

25. Reasons for Submission

Periodic Safety Update Report for July 1, 2013 through June 30, 2014

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

27. This application is *(Select one)* ☐ Paper ☐ Paper and Electronic ☐ Electronic

28. Number of Volumes Submitted

29. 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 *(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)*

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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.)

NOTE: No changes to Establishment Information and Cross References from that previously provided are being made in support of this PSUR submission.

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31. 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)*

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)*: Periodic Safety Update Report	

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)*
Karla Werre, MBA, RAC(US), Manager, Regulatory Affairs	08/25/2014

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
314-654-3517	314-654-6496	karla.werre@mallinckrodt.com

37. Address of Applicant's Responsible Official

Address 1 *(Street address, P.O. box, company name c/o)*: 675 McDonnell Boulevard		
Address 2 *(Apartment, suite, unit, building, floor, etc.)*:		
City: Hazelwood	State/Province/Region: MO	
Country: USA	ZIP or Postal Code: 63042	

38. Signature of Applicant's Responsible Official or Other Authorized Official	39. Countersignature of Authorized U.S. Agent
Sign	Sign
***Redacted - PII**	

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