REGULATORY SUBMISSION REVIEW FORM

Type of Submission:	Periodic Safety Update Report
Product Name:	Oxycodone HCL Extended-Release Tablets 10 mg, 20 mg, 40mg and 80 mg
Application & Sequence:	ANDA 077822 & Sequence 0021
Additional Information:	

Your signature below indicates that you have reviewed the document identified above with respect to your area of responsibility and have directed the document author to correct any identified errors.

Reviewers	Signature	Date Signed
Regulatory Affairs Author	Jessica Emerson Signature Jessica Emerson	11/22/10
Regulatory Affairs Draft Review	Stacy Holper Signature Stacy Holper	11-22-10
Manager, Regulatory Affairs	Bill Reinhart Signature Bill Reinhart	28 APR 11
Director, Regulatory Affairs	Jim Brodack Signature James R Brodack	20 May 2011

Return to: **Location: 30-X**

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, Parts 314 & 601)

Form Approved: OMB No. 0910-0338
Expiration Date: September 30, 2008
See OMB Statement on page 2.

FOR FDA USE ONLY

APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT	DATE OF SUBMISSION
Mallinckrodt Inc.	11/22/2010
TELEPHONE NO. *(Include Area Code)*	**FACSIMILE** *(FAX)* **Number** *(Include Area Code)*
314-654-2000	314-654-6496

APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued):*

675 McDonnell Boulevard
Hazelwood, MO 63042

AUTHORIZED U.S. AGENT NAME & ADDRESS *(Number, Street, City, State, ZIP Code, telephone & FAX number)* IF APPLICABLE

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER *(If previously issued)*: 077822

ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)*	PROPRIETARY NAME *(trade name)* IF ANY
Oxycodone Hydrochloride Extended Release Tablets	

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)*: Morphinan-6-one, 4,5-epoxy-14-hydroxy-3-methoxy-17

CODE NAME *(If any)*:

DOSAGE FORM:	STRENGTHS:	ROUTE OF ADMINISTRATION:
Tablet	10 mg, 20 mg, 40 mg, 80 mg	Oral

(PROPOSED) INDICATION(S) FOR USE: Management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for extended

APPLICATION DESCRIPTION

APPLICATION TYPE *(check one)*
- ☐ NEW DRUG APPLICATION (CDA, 21 CFR 314.50)
- ☑ ABBREVIATED NEW DRUG APPLICATION (ANDA, 21 CFR 314.94)
- ☐ BIOLOGICS LICENSE APPLICATION (BLA, 21 CFR Part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE ☐ 505 (b)(1) ☐ 505 (b)(2)

IF AN ANDA, OR 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION

Name of Drug: Oxycontin (NDA #20-553) Holder of Approved Application: Purdue Pharma

TYPE OF SUBMISSION *(check one)*
- ☐ ORIGINAL APPLICATION
- ☐ AMENDMENT TO APENDING APPLICATION
- ☐ RESUBMISSION
- ☐ PRESUBMISSION
- ☐ ANNUAL REPORT
- ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT
- ☐ EFFICACY SUPPLEMENT
- ☐ LABELING SUPPLEMENT
- ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT
- ☑ OTHER: Safety Update

IF A SUBMISSION OF PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION:

IF A SUPPLEMENT, IDENTIFY THE APPROPRIATE CATEGORY ☐ CBE ☐ CBE-30 ☐ Prior Approval (PA)

REASON FOR SUBMISSION: Periodic Safety Update Report

PROPOSED MARKETING STATUS *(check one)* ☑ PRESCRIPTION PRODUCT (Rx) ☐ OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED: 1 THIS APPLICATION IS ☐ PAPER ☐ PAPER AND ELECTRONIC ☑ ELECTRONIC

ESTABLISHMENT INFORMATION (Full establishment information should be provided in the body of the Application.)
Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

Mallinckrodt Inc. ,172 Railroad Avenue, Hobart, NY 13788
Contact: Gary Boemer, Phone: (607) 538-2255, Fax: (607)-538-2500, Email: gary.boemer@covidien.com
Establishment Registration: 1317295 (CFN)

Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)

N/A

This application contains the following items: *(Check all that apply)*	
☐	1. Index
☐	2. Labeling *(check 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 (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 which claims the drug (21 U.S.C. 355(b) or (c))
☐	14. A patent certification with respect to any patent which claims the drug (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 (Form FDA 3397)
☐	19. Financial 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.

SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	TYPED NAME AND TITLE	DATE:
Jessica Emerson	Jessica Emerson, Regulatory Associate II	11/22/2010

ADDRESS *(Street, City, State, and ZIP Code)*	Telephone Number
675 McDonnell Boulevard, Hazelwood, MO 63042	314-654-0238

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Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research (HFM-99)
1401 Rockville Pike
Rockville, MD 20852-1448

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MALLINCKRODT INC.

COVIDIEN

PERIODIC SAFETY UPDATE REPORT

November 22, 2010

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Attention: Document Control Room
7620 Standish Place
Rockville, MD 20855

RE: ANDA 077822 Quarterly Adverse Drug Experience Report
Oxycodone HCl Extended-Release Tablets, 10 mg, 20 mg, 40 mg, 80 mg
Reporting Period: July 24, 2010 through October 23, 2010

Dear Sir or Madam:

This periodic safety report is filed under 21 CFR 314.80(c)(2) and 314.98. Please refer to the Mallinckrodt Inc, a Covidien company ANDA 077822 Oxycodone Hydrochloride Extended-Release Tablets, 10 mg, 20 mg, 40 mg, and 80 mg manufactured at the Mallinckrodt Inc. facility in Hobart, NY.

This periodic safety report is provided as sequence 0021 and submitted via the Electronic Submissions Gateway (approximately 1 MB). The submission is certified to be free from virus infection using McAfee® VirusScan®, Enterprise ver. 8.7*i*. The technical point of contact for this submission is Jeremy Grise, with whom contact may be made at (314) 654-8259, by fax at (314) 654-6496, or via e-mail at jeremy.grise@covidien.com.

Should you have any questions or need additional information please contact Becky Welton, Manager, Regulatory Affairs by telephone at (314) 654-5607, by fax at (314) 654-6496, or by email at becky.welton@covidien.com.

Sincerely,

Jessica Emerson

Jessica Emerson
Regulatory Affairs Associate II
Email: jessica.emerson@covidien.com

cc: FDA – Office of Surveillance and Epidemiology [CFR§314.98(b)]

675 MCDONNELL BLVD.
HAZELWOOD, MO
63042

314-654-2000 [T]

WWW.COVIDIEN.COM

Verification of Published Output Checklist Form

Item to be Checked	Total #	Percentage to be Checked	Actual Percentage Checked
Signature Manifestations	N/A		
Cross-references	N/A		
Front Pages	N/A		
Table of Contents Entries	N/A		
Table of Contents Hyperlinks	ALL	100%	100%
Document Hyperlinks	ALL	100%	100%
PDF Document Properties	N/A		

Completed by: Jessica Ernesto

Date: 11/22/10

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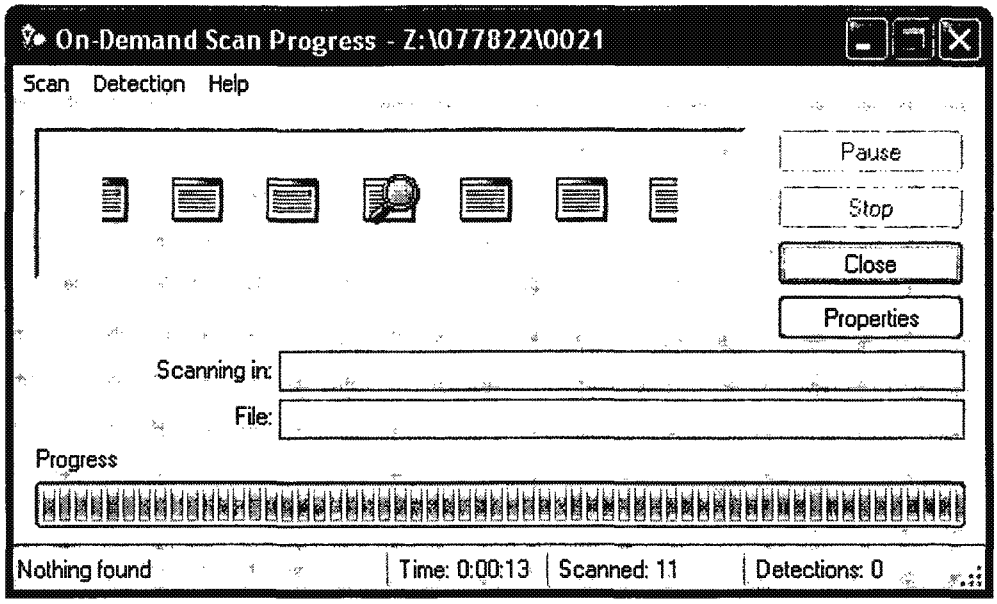

Performed by:

Jessica Emerson
Regulatory Affairs Associate

11/22/10
Date

077822 0021 CDER Acknowledgement.txt

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