NOTICE
Adverse Event and Product Complaint Reporting

Purdue has obligations to monitor Adverse Events and Product Complaints that are associated with any product included in Attachment A. In order to assist us, while you are engaged by Purdue in any capacity, please follow the procedures described in this document and in the corresponding section of Purdue's Healthcare Law Compliance Policies (which can be accessed by clicking on this link : HCLC Policies).

An **Adverse Event (AE)** is defined as any untoward medical occurrence associated with the use of a drug (or biological product) in humans, whether or not considered drug/product related ***[21 CFR 312.32(a)].*** An AE can be any unfavorable or unintended sign (e.g. abnormal laboratory finding), symptom (e.g. failure of expected pharmacological action), or disease temporally associated with the use of a drug/product, and does not imply any judgment about causality. An adverse event can occur with any use of the drug including off-label use, misuse, abuse, or use in combination with another drug; and, with any route of administration, formulation, or dose, including an overdose (whether accidental or intentional). *[Reference is made to **21 CFR § 310.305(b) and § 314.80(a)**]*.

Examples of Adverse Events include:

- Exposure during pregnancy
- Worsening of pre-existing condition
- Drug interactions
- Medication errors
- Any hospitalizations or surgery
- Death

In the context of adverse event reporting, HIPAA specifically permits disclosure of protected health information without authorization that is relevant to the report. Please provide as much information as possible concerning the following 4 core elements of a [reportable] adverse event report:

1. Adverse Event (AE): description of the event(s) (including AEs listed in the package insert)
2. Patient(s): Gender, age, age group, initials or name
3. Product(s): Brand name, generic name, active ingredient, lot number
4. Reporter: Full name and contact information (phone number and current mailing address)

If you are uncertain if something should be reported as an AE or not, please err on the side of caution and report the information and we will follow up with the reporter, as necessary.

A **Product Complaint (PC)** is any untoward occurrence with the physical characteristics of a product or with the product's packaging, labeling, immediate container, closure, or contents.

Please provide as much information as possible concerning the:

1. Description of the potential PC
2. Product: Brand name, generic name, active ingredient, lot number
3. Reporter: Full name and contact information (phone number and current mailing address)

If the product does not perform in the manner that the product label or information indicates it should, that is also an Adverse Event or Product Complaint.

You must report any Adverse Event or Product Complaint associated with any product included in Attachment A, or any product of the same active ingredient when the brand and manufacturer of that product are unknown. This information should be reported regardless of whether the person providing the information (reporter) thinks the issue is related to the product or not.

If you learn of an Adverse Event or Product Complaint**, report the incident as soon as possible, but no later than 48 hours after learning of it**.

If the AE/PC was received as a hard copy (e.g. letter):

- ✓ Immediately date stamp any hard copy information.
- ✓ Once hard copy information is date stamped, the document is to be scanned and forwarded to Drug Safety and/or Product Monitoring via e-mail or fax (see **Ways to Report an AE/PC** below).
- ✓ After e-mailing or faxing, the original hard copy is to be forwarded to Drug Safety or Product Monitoring via interoffice mail. Please do not address the hard copy to any specific individual.

Ways to Report an AE/PC:

Report via **<u>one</u>** of the following:

Phone: (888) 726-7535, prompt 2 (to report an Adverse Event) or prompt 3 (to report a Product Complaint)

Fax: (203) 588-6395

Electronic Reporting:

1) Send an email to report an adverse or unwanted experience associated with the use of a Purdue product to the "Drug Safety and Pharmacovigilance" or "AE Report" address in Outlook (or email to: AEReport2@pharma.com).
2) Send an email to report a product complaint to the "Product Complaints" address in Outlook (or email to: productcomplaints@pharma.com).
3) Individuals with access to the Phoenix system should use Phoenix.

Thank you for your attention to this important matter.

Purdue Drug Safety & Pharmacovigilance
Purdue Corporate Quality Assurance

Attachment A
Product List: Dec 2016

Purdue Prescription Products

Butrans®
(buprenorphine) Transdermal System CIII

Hysingla® ER
(hydrocodone bitartrate) Extended-Release Tablets CII

Dilaudid® Oral Liquid
Dilaudid® Tablets
Dilaudid® Injection
Dilaudid-HP® Injection
(hydromorphone hydrochloride) CII

Intermezzo®
(zolpidem tartrate) Sublingual Tablets CIV

MS Contin®
(morphine sulfate extended-release tablets) CII

OxyContin®
(oxycodone hydrochloride) Extended-Release Tablets CII

Purdue Authorized Generic Products

Oxycodone extended-release tablets CII

Purdue Over-the-Counter Products
Betadine®
Betadine® Solution
Betadine® Solution SwabAids
Betadine® Surgical Scrub
Betadine® Spray
Betadine® Skin Cleanser
Betadine® Solution Swabsticks
Povidone iodine
Betasept® Surgical Scrub
Chlorhexidine gluconate
Colace® Capsules
Colace Clear® Soft Gels
Docusate sodium

Peri-Colace® Tablets
Docusate sodium and standardized senna concentrate

Senokot® Tablets
SenokotXTRA® Tablets
Standardized senna concentrate

Senokot-S® Tablets
Standardized senna concentrate and docusate sodium

Slow-Mag® Tablets
Magnesium chloride

SVC Pharma L.P.
Dronabinol capsules

Rhodes Pharmaceuticals L.P.
Aptensio XR™ (methyphenidate hydrochloride extended release) Capsules CII

Fenofibrate capsules
Fenofibrate tablets

Hydromorphone hydrochloride oral solution USP CII
Hydromorphone hydrochloride tablets CII

Hydrocodone/APAP tablets CII

Morphine sulfate extended-release tablets CII
Morphine sulfate Oral Solution CII

Oxycodone and Acetaminophen tablets CII

Oxycodone hydrochloride immediate-release tablets CII

Theophylline extended-release tablets