Message

From: Polster, Natasha [tasha.polster@walgreens.com]
Sent: 10/12/2016 9:19:52 PM
To: Coyle, Justin [justin.coyle@walgreens.com]; Polster, Natasha [tasha.polster@walgreens.com]; Daugherty, Patricia [patricia.daugherty@walgreens.com]
CC: House, Emily [emily.house@walgreens.com]; Patel, Nish [nish.patel@walgreens.com]
Subject: FW: Purdue Compass communication - review requested
Attachments: Walgreen Co OTH092316 CW2320629 (AB.LLS) Exhibit 2 to MSA - OADP Communi....docx

+ Justin

Greg-
A couple questions, what is the intent of the communication/education? On the part that says Walgreens will send out the information in their weekly communications to our teams, is that a one-time message?

Regards,
Tasha Polster, RPh
Senior Director, Pharmacy & Retail Operations Compliance Execution

Walgreen Co. | 200 Wilmot Rd. MS 2194, Deerfield, IL 60015
Telephone 847 315 3379
Cell 847 858 2721

Member of Walgreens Boots Alliance

From: Pankow, Greg
Sent: Wednesday, October 12, 2016 7:31 AM
To: Polster, Natasha; Daugherty, Patricia
Cc: House, Emily; Patel, Nish
Subject: Purdue Compass communication - review requested

Good Morning,

Please find attached a Compass communication that Purdue is willing to fund for $25,000. I'm hoping to gain your approval of the content before we send it out. Please let me know if it's approved from your perspective or is you have any concerns.

Many Thanks, greg

Exhibit 2
to
Product Update Master Services Agreement

This Exhibit 2 ("Exhibit 2") is effective as of October 10, 2016 ("Exhibit Effective Date") and is hereby incorporated into the Product Update Master Services Agreement, dated March 17, 2015, by and between **Purdue Pharma, L.P.** ("Client") and **Walgreen Co**. ("Walgreens").

1. SERVICES:
Walgreens will create a Communication for the following pharmaceutical product:

Manufacturer: Client
Product Brand Name: No brand
Generic Name:
Communication: To inform Walgreens retail pharmacists of the technologies and policy around opioids with abuse-deterrent properties (the "Communication")

Based on the information provided by Client, Walgreens will develop the Communication for the Product. In addition, Walgreens will post the Communication as a MPU Alert on Walgreens' Intranet for a minimum of six months. At the time of posting, Walgreens will send a message to its pharmacies informing them of the Communication in the weekly electronic pharmacy update bulletin distributed to Walgreens' retail pharmacies. A copy of the Communication is attached below in the form of Attachment

2. TOTAL FEE:

The total fee payable by Client to Walgreens to develop and publish the Communication (including development and maintenance of the Communication) shall be $25,000. This total fee is not dependent on any volume of the Product prescriptions dispensed. The parties agree that the total fee is a fair market value in an arms-length transaction for the services being provided. The parties acknowledge that the service fee received by Walgreens from Client is intended solely for payment in consideration for the Communication services described herein and do not exceed that which is reasonably necessary to accomplish the parties' commercially reasonable business purpose pursuant to this Exhibit 2. These fees do not reflect a direct or indirect discount, rebate, or other price reduction on the purchase price of any product or goods manufactured or sold by Client or its affiliates to Walgreens, if any, and will not be used in such a manner either directly or indirectly

3. TIME LINE FOR DEVELOPMENT/IMPLEMENTATION:

Walgreens shall submit a draft of the Communication to Client for review prior to printing and distribution. Walgreens shall finalize the Communication (including making any revisions requested by Client that Walgreens deems appropriate) and Client shall approve the pharmacy update on or about November 1, 2016. Client reserves the right to withhold approval if required changes are not made as requested. If such occurs, Walgreens agrees it will not publish the Communication.

The Communication shall be published on or about November 21, 2016.

Signature page follows

IN WITNESS WHEREOF, the parties hereto have caused this Exhibit 2 to be executed by their duly authorized representatives as of the Exhibit Effective Date.

WALGREEN CO.	**PURDUE PHARMA, L.P.**
By: _____	By: _____
Printed Name: _____	Printed Name: _____
Title: _____	Title: _____

Overview of FDA 2015 Guidance for Industry

Abuse-Deterrent Opioids — Evaluation and Labeling

"Prescription opioid products are an important component of modern pain management. However, abuse and misuse of these products have created a serious and growing public health problem. One potentially important step towards the goal of creating safer opioid analgesics has been the development of opioids that are formulated to deter abuse. FDA considers the development of these products a high public health priority."[1]

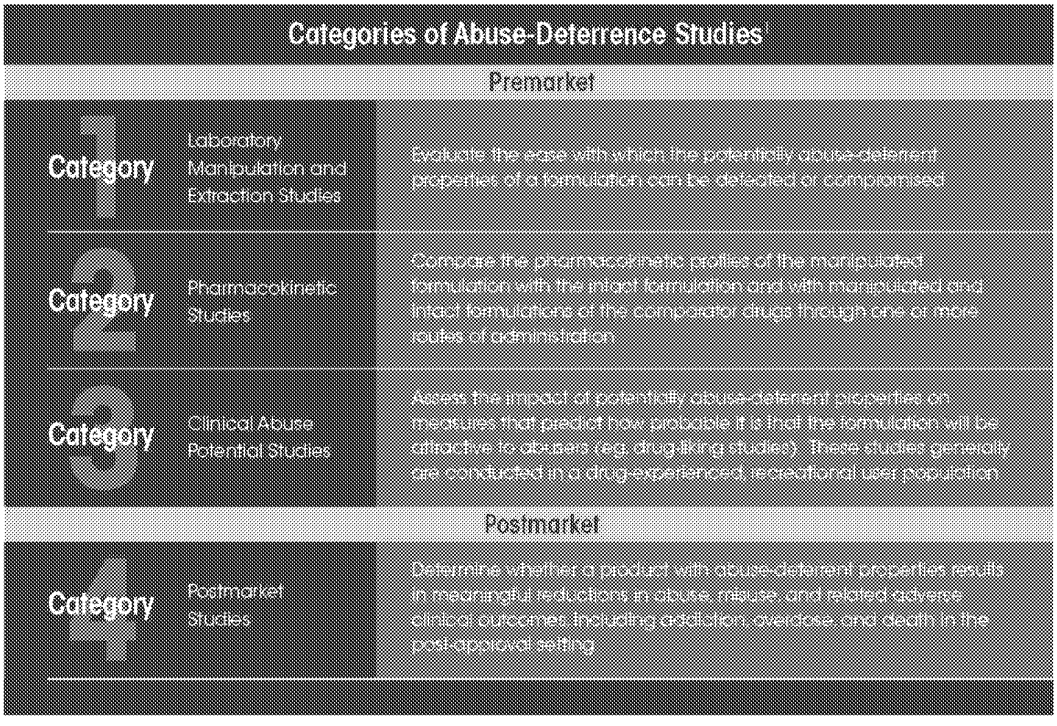
In April 2015 the FDA issued a final guidance to assist industry in developing opioid drug products with potentially abuse-deterrent properties.[2]

The Guidance describes categories of abuse-deterrent products, the premarket and postmarket studies that should be performed to assess the impact of a potentially abuse-deterrent product, and provides information about labeling for abuse-deterrent products. It can be accessed at http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm334743.pdf[1]

Abuse-Deterrent Formulations

Opioid products can be abused in a number of ways. Abuse-deterrent technologies should target known or expected routes of abuse relevant to the proposed product. As a general framework, abuse-deterrent formulations can currently be categorized as follows:[1]

1. ***Physical/chemical barriers*** – Physical and chemical barriers can limit drug release following mechanical manipulation, or change the physical form of a drug, rendering it less amenable to abuse.[1]
2. ***Agonist/antagonist combinations*** – An opioid antagonist can be added to interfere with, reduce, or defeat the euphoria associated with abuse. The antagonist can be sequestered and released only upon manipulation of the product.[1]
3. ***Aversion*** – Substances can be added to the product to produce an unpleasant effect if the dosage form is manipulated or is used at a higher dosage than directed. For example, the formulation can include a substance irritating to the nasal mucosa if ground and snorted.[1]
4. ***Delivery System (including use of depot injectable formulations and implants)*** – Certain drug release designs or the method of drug delivery can offer resistance to abuse. For example, sustained-release depot injectable formulation or a subcutaneous implant may be difficult to manipulate.[1]
5. ***New molecular entities and prodrugs*** – The properties of a new molecular entity (NME) or prodrug could include the need for enzymatic activation, different receptor binding profiles, slower penetration into the central nervous system, or other novel effects. Prodrugs with abuse-deterrent properties could provide a chemical barrier to the *in vitro* conversion to the parent opioid, which may deter the abuse of the parent opioid.[1]
6. ***Combination*** – Two or more of the above methods could be combined to deter abuse.[1]
7. ***Novel approaches*** – This category encompasses novel approaches or technologies that are not captured in the previous categories.[1]



Labeling[1]

FDA encourages sponsors to propose labeling that sets forth the results of *in vitro*, pharmacokinetic, clinical abuse potential and formal postmarket studies and appropriately characterizes the abuse-deterrent properties of a product.[1]

Labeling should reflect the predictive quality of premarket studies and include results of relevant completed postmarket studies.[1]

The Guidance notes, "FDA will take a flexible, adaptive approach to the evaluation and labeling of abuse-deterrent opioid products. FDA expects sponsors to update their formulations to take advantage of technological improvements and further expects to allow labeling statements related to abuse deterrence commensurate with those advances."[1]

For more information, please visit http://www.fda.gov/downloads/drugs/guidancecomplianceregulatory information/guidances/ucm334743.pdf

References

1. Center for Drug Evaluation and Research (CDER), US Food and Drug Administration, US Department of Health and Human Services. *Guidance for Industry: Abuse-Deterrent Opioids—Evaluation and Labeling*. Silver Spring, MD: US Department of Health and Human Services; 2015. Available at: http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm334743.pdf. Accessed August, 2015.
2. US Food and Drug Administration. FDA News Release. FDA issues final guidance on the evaluation and labeling of abuse-deterrent opioids. FDA Website. Available at: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm440713.htm. Accessed August, 2015.

www.TeamAgainstOpioidAbuse.com