CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-272

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

EXCLUSIVITY SUMMARY

NDA # 022272 SUPPL # HFD # 170

Trade Name OxyContin

Generic Name Oxycodone Hydrochloride Controlled-Release Tablets

Applicant Name Purdue Pharma L.P.

Approval Date, If Known April 5, 2010

PART I IS AN EXCLUSIVITY DETERMINATION NEEDED?

1. An exclusivity determination will be made for all original applications, and all efficacy supplements. Complete PARTS II and III of this Exclusivity Summary only if you answer "yes" to one or more of the following questions about the submission.

a) Is it a 505(b)(1), 505(b)(2) or efficacy supplement?

YES ☒ NO ☐

If yes, what type? Specify 505(b)(1), 505(b)(2), SE1, SE2, SE3,SE4, SE5, SE6, SE7, SE8

505(b)(1)

c) Did it require the review of clinical data other than to support a safety claim or change in labeling related to safety? (If it required review only of bioavailability or bioequivalence data, answer "no.")

YES ☐ NO ☒

If your answer is "no" because you believe the study is a bioavailability study and, therefore, not eligible for exclusivity, EXPLAIN why it is a bioavailability study, including your reasons for disagreeing with any arguments made by the applicant that the study was not simply a bioavailability study.

This is a reformulation of the original OxyContin (under NDA 020553). The new formulation was compared to the original formulation in comparative bioavailability studies. This new formulation was shown to be bioequivalent to the original formulation. No clinical studies were performed.

If it is a supplement requiring the review of clinical data but it is not an effectiveness supplement, describe the change or claim that is supported by the clinical data:

d) Did the applicant request exclusivity?

YES ☐ NO ☒

If the answer to (d) is "yes," how many years of exclusivity did the applicant request?

e) Has pediatric exclusivity been granted for this Active Moiety?

YES ☐ NO ☒

If the answer to the above question in YES, is this approval a result of the studies submitted in response to the Pediatric Written Request?

IF YOU HAVE ANSWERED "NO" TO ALL OF THE ABOVE QUESTIONS, GO DIRECTLY TO THE SIGNATURE BLOCKS AT THE END OF THIS DOCUMENT.

2. Is this drug product or indication a DESI upgrade?

YES ☐ NO ☒

IF THE ANSWER TO QUESTION 2 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8 (even if a study was required for the upgrade).

PART II FIVE-YEAR EXCLUSIVITY FOR NEW CHEMICAL ENTITIES
(Answer either #1 or #2 as appropriate)

1. Single active ingredient product.

Has FDA previously approved under section 505 of the Act any drug product containing the same active moiety as the drug under consideration? Answer "yes" if the active moiety (including other esterified forms, salts, complexes, chelates or clathrates) has been previously approved, but this particular form of the active moiety, e.g., this particular ester or salt (including salts with hydrogen or coordination bonding) or other non-covalent derivative (such as a complex, chelate, or clathrate) has not been approved. Answer "no" if the compound requires metabolic conversion (other than deesterification of an esterified form of the drug) to produce an already approved active moiety.

YES ☒ NO ☐

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA

#(s).

Appl No	TE Code	RLD	Active Ingredient	Dosage Form; Route	Strength	Proprietary Name	Applicant
A040199	AA	No	ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE	CAPSULE; ORAL	500MG;5MG	OXYCODONE AND ACETAMINOPHEN	ACTAVIS TOTOWA
A040289	AA	No	ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE	CAPSULE; ORAL	500MG;5MG	OXYCODONE AND ACETAMINOPHEN	DURAMED PHARMS BARR
A040303	AA	No	ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE	CAPSULE; ORAL	500MG;5MG	OXYCODONE AND ACETAMINOPHEN	ENDO PHARMS
A040257	AA	No	ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE	CAPSULE; ORAL	500MG;5MG	OXYCODONE AND ACETAMINOPHEN	MALLINCKRODT
A088790	AA	Yes	ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE	CAPSULE; ORAL	500MG;5MG	TYLOX	ORTHO MCNEIL JANSSEN
A040061	AA	No	ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE	CAPSULE; ORAL	500MG;5MG	ROXILOX	ROXANE
A040106	AA	No	ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE	CAPSULE; ORAL	500MG;5MG	OXYCODONE AND ACETAMINOPHEN	VINTAGE PHARMS
A040234	AA	No	ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE	CAPSULE; ORAL	500MG;5MG	OXYCODONE AND ACETAMINOPHEN	WATSON LABS
A040680	AA	No	ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE	SOLUTION; ORAL	325MG/5ML;5MG/5ML	OXYCODONE AND ACETAMINOPHEN	MALLINCKRODT
A089351	AA	Yes	ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE	SOLUTION; ORAL	325MG/5ML;5MG/5ML	ROXICET	ROXANE
A040203	AA	No	ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE	TABLET; ORAL	325MG;5MG	OXYCODONE AND ACETAMINOPHEN	ACTAVIS TOTOWA
A040778	AA	No	ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE	TABLET; ORAL	325MG;10MG	OXYCODONE AND ACETAMINOPHEN	AMNEAL PHARMS NY

A040777	**AA**	No	ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE	TABLET; ORAL	325MG;5MG	OXYCODONE AND ACETAMINOPHEN	AMNEAL PHARMS NY
A040789	**AA**	No	ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE	TABLET; ORAL	500MG;7 5MG	OXYCODONE AND ACETAMINOPHEN	AMNEAL PHARMS NY
A040789	**AA**	No	ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE	TABLET; ORAL	650MG;10MG	OXYCODONE AND ACETAMINOPHEN	AMNEAL PHARMS NY
A090177	**AA**	No	ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE	TABLET; ORAL	325MG;10MG	OXYCODONE AND ACETAMINOPHEN	COASTAL PHARMS
A090177	**AA**	No	ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE	TABLET; ORAL	325MG;2 5MG	OXYCODONE AND ACETAMINOPHEN	COASTAL PHARMS
A090177	**AA**	No	ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE	TABLET; ORAL	325MG;5MG	OXYCODONE AND ACETAMINOPHEN	COASTAL PHARMS
A090177	**AA**	No	ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE	TABLET; ORAL	325MG;7 5MG	OXYCODONE AND ACETAMINOPHEN	COASTAL PHARMS
A090177	**AA**	No	ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE	TABLET; ORAL	500MG;7 5MG	OXYCODONE AND ACETAMINOPHEN	COASTAL PHARMS
A090177	**AA**	No	ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE	TABLET; ORAL	650MG;10MG	OXYCODONE AND ACETAMINOPHEN	COASTAL PHARMS
A040434	**AA**	Yes	ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE	TABLET; ORAL	325MG;10MG	PERCOCET	ENDO PHARMS
A040330	**AA**	Yes	ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE	TABLET; ORAL	325MG;2 5MG	PERCOCET	ENDO PHARMS
A040330	**AA**	Yes	ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE	TABLET; ORAL	325MG;5MG	PERCOCET	ENDO PHARMS
A040434	**AA**	Yes	ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE	TABLET; ORAL	325MG;7 5MG	PERCOCET	ENDO PHARMS

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