# CENTER FOR DRUG EVALUATION AND RESEARCH

**APPLICATION NUMBER:** 

201280Orig1s000

**OTHER REVIEW(S)** 



### **Attachment B: Sample PMR/PMC Development Template**

This template should be c PMR/PMC in the Action	ompleted by the PMR/PMC Development Co Package.	oordinator and included for <u>each</u>
PMR/PMC Description:	An epidemiologic study to compare the risk severe cutaneous reactions in type 2 diabetic in type 2 diabetics exposed to other antidial	cs exposed to linagliptin to the risk
PMR/PMC Schedule Mile	estones: Final Protocol Submission: Study/Ttrial Completion: Final Report Submission: Other: NA	05/30/2012 11/30/2018 6/30/2019
pre-approval requiren  Unmet need  Life-threatenin  Long-term dat  Only feasible  Prior clinical of  Small subpopt  Theoretical co  Other  Linagluptin is a dipereported in the postnapproved DPP-4 inhibited development program was considered a seri	a needed to conduct post-approval experience indicates safety alation affected	persensitivity reactions have been in, which are the only FDA-irred in the linagliptin clinical intients on linagliptin; one of these if skin exfoliation that were
severe hypersensitive but this study will here.  2. Describe the particular study will be the particula	ity reactions with linagliptin (if such an associate characterize this potential risk.  r review issue and the goal of the study/clinic ribe the risk. If the FDAAA PMR is created	ciation exists) appears to be rare,
See response under severe hypersensitiv	Question 1. The goal of the epidemiological sity reactions and severe cutaneous reactions as exposed to other antidiabetic medications.	study is to compare the risk of



If the study/clinical trial is a PMR, check the applicable regulation.  If not a PMR, skip to 4.		
- Which regulation?  Accelerated Approval (subpart H/E)		
Animal Efficacy Rule		
☐ Pediatric Research Equity Act ☐ FDAAA required safety study/clinical trial		
1 DAAA required sarcty study/eninear trial		
- If the PMR is a FDAAA safety study/clinical trial, does it: (check all that apply)		
Assess a known serious risk related to the use of the drug?  Assess signals of serious risk related to the use of the drug?		
☐ Identify an unexpected serious risk when available data indicate the potential for a serious		
risk?		
- If the PMR is a FDAAA safety study/clinical trial, will it be conducted as:		
Analysis of spontaneous postmarketing adverse events?		
<b>Do not select the above study/clinical trial type if:</b> such an analysis will not be sufficient to assess or identify a serious risk		
<u> </u>		
Analysis using pharmacovigilance system? <b>Do not select the above study/clinical trial type if:</b> the new pharmacovigilance system that the		
FDA is required to establish under section 505(k)(3) has not yet been established and is thus		
not sufficient to assess this known serious risk, or has been established but is nevertheless not sufficient to assess or identify a serious risk		
<u> </u>		
Study: all other investigations, such as investigations in humans that are not clinical trials as defined below (e.g., observational epidemiologic studies), animal studies, and laboratory		
experiments?		
<b>Do not select the above study type if:</b> a study will not be sufficient to identify or assess a serious risk		
<u></u>		
Clinical trial: any prospective investigation in which the sponsor or investigator determines the method of assigning investigational product or other interventions to one or more human		
subjects?		
What type of study or clinical trial is required or agreed upon (describe and check type below)? If the		
study or trial will be performed in a subpopulation, list here.		
Risk of severe hypersensitivity reactions and severe cutaneous reactions.		
Required		
<ul> <li>         □ Observational pharmacoepidemiologic study     </li> </ul>		
Registry studies		
☐ Primary safety study or clinical trial ☐ Pharmacogenetic or pharmacogenomic study or clinical trial if required to further assess safety		
☐ Thorough Q-T clinical trial		
Nonclinical (animal) safety study (e.g., carcinogenicity, reproductive toxicology)		

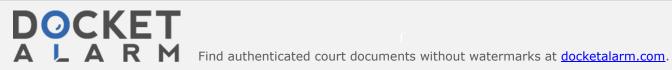


4.

Continuation of Question 4	
<ul> <li>Nonclinical study (laboratory resistance, rece</li> <li>□ Pharmacokinetic studies or clinical trials</li> <li>□ Drug interaction or bioavailability studies or</li> <li>□ Dosing trials</li> <li>□ Additional data or analysis required for a pre (provide explanation)</li> </ul>	
Meta-analysis or pooled analysis of previous Immunogenicity as a marker of safety Other (provide explanation)	studies/clinical trials
Agreed upon:	
Quality study without a safety endpoint (e.g.,  Pharmacoepidemiologic study not related to a background rates of adverse events)  Clinical trials primarily designed to further de different disease severity, or subgroup) that a  Dose-response study or clinical trial performation.  Nonclinical study, not safety-related (specify)	eafe drug use (e.g., natural history of disease, efine efficacy (e.g., in another condition, are NOT required under Subpart H/E ed for effectiveness
Other	
<ul> <li>5. Is the PMR/PMC clear, feasible, and appropriate</li> <li>☑ Does the study/clinical trial meet criteria for</li> <li>☑ Are the objectives clear from the description</li> <li>☑ Has the applicant adequately justified the ch</li> <li>☑ Has the applicant had sufficient time to revie feasibility, and contribute to the development</li> </ul>	PMRs or PMCs? of the PMR/PMC? oice of schedule milestone dates? ew the PMRs/PMCs, ask questions, determine
	ty and consistency, and is necessary to further refine or to ensure consistency and reliability of drug
(signature line for BLAs)	



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/s/
AMY G EGAN 05/01/2011



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