

Miller, Diane M. (CDC/NIOSH/EID)

From: Joel.Sigler@kp.org
Sent: Thursday, September 20, 2007 8:29 PM
To: NIOSH Docket Office (CDC)
Cc: Erica.Stewart@kp.org; Donald.R.Kaplan@kp.org
Subject: Fw: Kaiser Permanente comment on NIOSH haz drug list
Attachments: NIOSH BCG comment submission.xls

Attached please find our comments regarding Appendix A of the NIOSH Hazardous Drug Alert.

We appreciate the opportunity to submit our comments.

Please do not hesitate to contact me if you have any questions.

-Joel

Joel Sigler
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10/15/2007

Drugs to Review 2006 Docket #NIOOSH-105

Reviewer : Erica Stewart, CIH; Joel Sigler; Donald Kaplan, PharmD

Affiliation : Kaiser Permanente

Send reviews to: niocindocket@cdc.gov

Proprietary Name	Established Name	Should this Drug be Included In the NIOSH Hazardous Drugs List?		Comments
		yes	no	
New FDA Drugs and Warnings Fitting NIOSH Criteria For Hazardous Drugs				
Abilify	aripiprazole			
Alimta	peginterferon			
Amnive	atacept			
Amniva	lubiprostone			
Apokyn	apomorphine HCl			
Aranon	inlarabine			
Avastin	bevacizumab			
Azilect	rasagiline mesylate			
Bacillus Calmette-Guerin			No	BCG is a live virus that represents a potential biological hazard during preparation. While BCG is an infection risk, it does not represent health concerns consistent with other hazardous drugs in Appendix A (carcinogen, teratogen, reproductive, toxicity). Based on cross-contamination concerns, manufacturer recommendations advise that BCG should not be prepared in the same areas where parenteral drugs are prepared. Current industry practice is to prepare live viruses, bacteria, and other organisms in areas segregated from chemotherapeutic drug preparation to prevent cross contamination. Safe BCG preparation requires controls appropriate for a biological hazard. Recommended controls in the NIOSH Alert do not effectively address cross contamination risks of preparing live viruses in the same area as other drugs. Overall, we recommend that BCG be removed from Appendix A based on: the risk of cross contamination and the need to segregate BCG from other drugs currently on the list during preparation; the biological health hazard risk that is not consistent with the types of health risks of other drugs currently on the list.
Baraclude	entecavir			
Chantix	varenicline			
Clofarabine	clofarabine			
Cidlar	amidarone HCl			
Cordarone	decitabine			
Dacogen	valproate Na			
Depacone	valproic acid			
Depakene	divalproex Na			
Depakote	medroxyprogesterone acetate			
Depo-Provera**	pimecrolimus			
Elidel	cetuximab			
Erbtux	ziprasidone			
Geodon	imatinib mesylate			
Gleevec	zalcitabine			
Hivid	topotecan HCl			
Hyacinth	mecasermin (rDNA origin)			
Increlex	palifermin			
Keprivance	cladribine			
Leustatin	eszopiclone			
Lunesta	pregalin			
Lyrica	strontium-89 chloride			
Melantron				

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Proprietary Name	Established Name	Should this Drug be Included in the NIOSH Hazardous Drugs List?		Comments
		Yes	No	
New FDA Drugs and Warnings Fitting NIOSH Criteria For Hazardous Drugs				
Mycamine	micafungin sodium			
Myozyme	alglucosidase alfa			
Nexavar	sorafenib			
Orencia	abatacept			
Paxil	paroxetine HCl			
Pentelate Calcium				
Trisodium				
Phlofidrin	portimer sodium			
Provera**	medroxyprogesterone acetate			
Quadramet	samarium 153 lexidronam			
Rapamune	sirolimus			
Revlimid	lenalidomide			
Risperdal Consta**	risperdone			
Risperdal**	risperdone			
Riluxan	riluximab			
Rozerem	ramelteon			
Seroquel	quetiapine fumarate			
Spiriva Handhaler	tiotropium bromide			
Sprycel	dasatinib			
Sustiva	efavirenz			
Sutent	suinilnib malate			
Tarceva	erlotinib HCl			
Tindamax	tindazole			
Tracleer	bosentan			
Tripletal	oxcarbazepine			
Typacil	tigecycline			
Tysabri	natalizumab			
Velcade	bortezomib			
Vidaza	azacitidine			
Viramune	nevirapine			
Viread	tenofovir			
Vision Blue	typan blue			
Zolniza	vorinostat			
Zonegran	zonisamide			
New FDA Drugs and Warnings Not Fitting NIOSH Criteria For Hazardous Drugs				
Actios	piofilazone HCl			
Actoplus Met	HCl			
	piofilazone HCl/ metformin			

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Proprietary Name	Established Name	Should this Drug be Included in the NIOSH Hazardous Drugs List ?		Comments
		yes	no	
New FDA Drugs and Warnings Fitting NIOSH Criteria For Hazardous Drugs				
Adderall	amphetamine			
Amphadase**	hyaluronidase			
Adirda	insulin glulisine			
Aplivus	tipranavir			
Aranesp	darbepoetin alfa			
Avandaryl	rosiglitazone maleate/ glimepiride			
Avonex	interferon beta 1a			
Belaseron	interferon beta 1b			
Byetta	exenatide			
Campral	acamprosate calcium			
Candis	casopfungin acetate			
ChirProSlim	human secretion			
Clozaril	clozapine			
Concerta*	methylphenidate HCl			
Cymbalta	duloxetine HCl			
Daytrana*	methylphenidate HCl			
Dexedrine	dextroamphetamine			
Dilaudid	hydromorphone HCl			
Diovan	valsartan			
Elaprase	idursulfate			
Elmiron	pentosan polysulfate Na			
Elspar	asparaginase			
Enablex	darifenacin HBr			
Epopan**	epoetin alfa			
Eraxis	andafungin			
Ethylol	amifostine			
Exjade	deferasirox			
Focalin	dexamethphenidate HCl			
Fortovase**	saquinavir mesylate			
Fostrenol	lanthanum carbonate hydrate			
Gabitril	tiagabine			
Herceptin	trastuzumab			
Humira	adalimumab			
Hyaluridase**	hyaluronidase			
Invirase**	saquinavir mesylate			
Iplex	mecasermin rinfabate			
Januvia	sitagliptin phosphate			
Ketek	telithromycin			

Drugs to Review 2008 Docket #NIOOSH-105
 Reviewer : Erica Stewart, CIH; Joel Styler; Donald Kaplan, PharmD
 Affiliation : Kaiser Permanente

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Proprietary Name	Established Name	Should this Drug be Included in the NIOOSH Hazardous Drugs List?		Comments
		yes	no	
New FDA Drugs and Warnings Fitting NIOOSH Criteria For Hazardous Drugs				
Lamictal	lamotrigine			
Levermir	insulin detemir			
Lucentis	ranibizumab			
Lumigan	bimatoprost			
Macugen	pegaptanib sodium			
Magnevist	gadopentetate dimeglumine			
Meladate*	methylphenidate HCl			
Methylin*	methylphenidate HCl			
Multihance	gabobenate dimeglumine			
Naglazyme	galsulfase			
Nevanac	nepalafenac			
Nexium	esomeprazole magnesium			
Noxafil	posaconazole			
NutresStore	L-glutamine			
Ornaocor	omega-3-acid ethylesters			
Opana	oxycodone HCl			
Pentolate Zinc				
Trisodium	lanisoprazole, naproxen			
Prevacid Naprelac	daunorubicin			
Prezista	ziconotide			
Prialt	epoetin alfa			
Prialt**				
Propranolol HCl	ranolazine			
Ramexa	irinotecan			
Rapamune	efalizumab			
Rapiviva	infliximab			
Remicade	methylphenidate HCl			
Ritalin*	trorsipium chloride			
Sanctura	cinacalcet HCl			
Sensipar	netazodone HCl			
Serzone	almoxetine HCl			
Strattera	pranlintide acetate			
Symtin	aprotinin			
Trasylol	telbivudine			
Tyzeka	panitumumab			
Vectibix	laprost			
Venlavis	kunecatechins			
Veregen	sciftenacin succinate			
VESTicare				

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Reviewer : Erica Stewart, CIH; Joel Stigler; Donald Kaplan, PharmD

Affiliation : Kaiser Permanente

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		Yes	No	
New FDA Drugs and Warnings Fitting NIOSH Criteria For Hazardous Drugs				
Vindex	didanosine			
Visudyne	verteporfin			
Vitrase	ovine hyaluronidase			
Weilburtin**	bupropion HCl			
Xifaxan	rifaximin			
Zaroxin	ethosuximide			
Zincocard	dextrazoxane			
Zypban**	bupropion HCl			
Zyprexa	olanzapine			

* = several proprietary names for same drug; ** = two proprietary names for same drug

ADDITIONAL COMMENTS