

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

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**From:** Erica.Stewart@kp.org  
**Sent:** Friday, September 21, 2007 11:38 AM  
**To:** Joel.Sigler@kp.org  
**Cc:** Donald.R.Kaplan@kp.org; NIOSH Docket Office (CDC)  
**Subject:** Re: Fw: Kaiser Permanente comment on NIOSH haz drug list  
**Attachments:** NIOSH BCG comment submission.xls

Thanks Joel, this looks great!

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Joel Sigler/PO/KAIPERM

09/20/2007 05:29 PM

To nicindocket@cdc.gov

Erica Stewart/PO/KAIPERM@KAIPERM, Donald R

cc Kaplan/CA/KAIPERM@KAIPERM

Subject Fw: Kaiser Permanente comment on NIOSH haz drug list

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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NEH&S Eastern Hub  
301-816-6225 (office)  
301-509-9893 (cell)

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](mailto:niocindocket@cdc.gov)

Proprietary Name	Established Name	Should this Drug be Included in the NIOSH Hazardous Drugs List ?		Comments
		Yes	No	
<b>New FDA Drugs and Warnings Fitting NIOSH Criteria For Hazardous Drugs</b>				
Abilify	aripiprazole			
Alimta	peginterferon alfa2a			
Amnive	amifampridine			
Amitiza	luliprostone			
Apokyn	apomorphine HCl			
Aranon	nelarabine			
Avastin	bevacizumab			
Azilect	rasagiline mesylate			
Bacillus Calmette-Guérin			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			
Coliar	clofarabine			
Cordarone	amiodarone HCl			
Dacogen	decitabine			
Depacone	valproate Na			
Depakene	valproic acid			
Depakote	divalproex Na			
Depo-Provera**	medroxyprogesterone acetate			
Elidel	pimecrolimus			
Erbilux	cetuximab			
Geodon	ziprasidone			
Gleevec	imatinib mesylate			
Hivid	zalcitabine			
Hydycantin	topotecan HCl			
Increlex	mecasermin (DNA origin)			
Keplivane	palifermin			
Leustatin	cladribine			
Lunesta	eszopiclone			
Lyfca	pregabalin			
Metastron	strontium-89 chloride			

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Proprietary Name	Established Name	Should this Drug be Included in the NIOSH Hazardous Drugs List?		Comments
		yes	no	
<b>New FDA Drugs and Warnings Fitting NIOSH Criteria For Hazardous Drugs</b>				
Mycamine	nicafungin sodium			
Myozyme	alglucosidase alfa			
Nexavar	sorafenib			
Orencea	abatacept			
Paxil	paroxetine HCl			
Pemolate Calcium				
Trisodium				
Photofrin	porfimer sodium			
Provera**	medroxyprogesterone acetate			
Quadramet	samarium 153 lexidronam			
Rapamune	sirilimus			
Revimid	tenatidomide			
Risperdal Consta**	risperidone			
Risperdal**	risperidone			
Rituxan	rituximab			
Rozerenm	ramelteon			
Seroquel	quetiapine fumarate			
Spiriva Handihaler	tiotropium bromide			
Sprycel	dasatinib			
Sustiva	efavirenz			
Sutent	sunitinib malate			
Tarceva	erlotinib HCl			
Tindamax	tinidazole			
Tracleer	bosentan			
Trileptal	oxcarbazepine			
Tyagacil	figicycline			
Tysabri	natalizumab			
Velcade	bortezomib			
Vidaza	azacitidine			
Viramune	nevirapine			
Viread	tenofovir			
Vision Blue	trypan blue			
Zolinza	vorinostat			
Zovigran	zonisamide			
<b>New FDA Drugs and Warnings Not Fitting NIOSH Criteria For Hazardous Drugs</b>				
Actoos	pioglitazone HCl			
Actoplus Met	HCl metformin			
	bioglitazone HCl			

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		Yes	No	
<b>New FDA Drugs and Warnings Fitting NIOSH Criteria For Hazardous Drugs</b>				
Adderall	amphetamine			
Amphadase**	hyaluronidase			
Apidra	insulin glulisine			
Aptivus	tipranavir			
Aranesp	darbepoetin alfa			
Avandaryl	rosiglitazone maleate/ glimepiride			
Avonex	interferon beta 1a			
Belasero	interferon beta 1b			
Byetta	exenatide			
Campral	acamprosate calcium			
Cancidas	caspofungin acetate			
ChilRhoStim	human secretion			
Clozaril	clozapine			
Concerta*	methylphenidate HCl			
Cymbalta	duloxetine HCl			
Daytrana*	methylphenidate HCl			
Dexedrine	dextroamphetamine			
Dilaudid	hydromorphone HCl			
Divan	valsartan			
Elaprase	idursulfate			
Elmiron	pentosan polysulfate Na			
Elspar	asparaginase			
Enablex	dantrolene HBr			
Epogen**	epoetin alfa			
Erraxis	andulafungin			
Ethylol	amifostine			
Exjade	deferasirox			
Focalin	dexamethphenidate HCl			
Fortovase**	saquinavir mesylate			
Fosterol	lanthanum carbonate hydrate			
Gabril	tiagabine			
Herceptin	trastuzumab			
Humira	adalimumab			
Hyalase**	hyaluronidase			
Invirase**	saquinavir mesylate			
Iplex	mecasermin rinfabate			
Januvia	sitagliptin phosphate			
Ketek	telithromycin			

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<b>New FDA Drugs and Warnings Fitting NIOSH Criteria For Hazardous Drugs</b>				
Lamictal	lamotrigine			
Levemir	insulin detemir			
Lucentis	ranibizumab			
Lumigan	bimatoprost			
Macugen	pegaptanib sodium			
Magnevist	gadopentetate dimeglumine			
Mecladate*	methylphenidate HCl			
Methylin*	methylphenidate HCl			
Multihance	gabobenate dimeglumine			
Naglazyme	galsulfase			
Nevanac	nefazafenac			
Nexium	esomeprazole magnesium			
Noxafil	posaconazole			
NutreStore	L-glutamine			
Omacor	omega-3-acid ethylesters			
Opana	oxycodone HCl			
Pentolate Zinc				
Trisodium				
Prevacid NaprafPAC	lansoprazole; naproxen			
Prezista	darunavir			
Prialt	ziconotide			
Procrit**	epoetin alfa			
Propranolol HCl				
Ranexa	ranolazine			
Rapamune	sirolimus			
Rapiviva	efalizumab			
Remicade	infliximab			
Ritalin*	methylphenidate HCl			
Sanctura	trospium chloride			
Sensipar	cinacalcet HCl			
Serzone	nefazodone HCl			
Strattera	atomoxetine HCl			
Synlin	pramirintide acetate			
Tasylol	aprotinin			
Tyzeka	telbivudine			
Vectivix	panitumumab			
Ventavis	iloprost			
Veregen	kunecatechins			
VEEicare	sulfafenach succinate			

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<b>New FDA Drugs and Warnings Fitting NIOSH Criteria For Hazardous Drugs</b>				
Videx	didanosine			
Visudyne	verteporfin			
Vitrase	ovine hyaluronidase			
Wellbutrin**	bupropion HCl			
Xifaxan	rifaximin			
Zarontin	ethosuximide			
Zinecard	dextroazoxane			
Zyban**	bupropion HCl			
Zyprexa	olanzapine			

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

**ADDITIONAL COMMENTS**