

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

From: michael.j.olson@gsk.com
Sent: Thursday, September 20, 2007 8:21 AM
To: NIOSH Docket Office (CDC)
Cc: steve.p.binks@gsk.com
Subject: 105 - HazDrug Update Comments
Attachments: Copy of PublicReviewForm2006-05-01-07 (Olson for GSK re Paroxetine).xls

For inclusion in public comments to US NIOSH Docket 105 regarding addition of certain drug products to the US NIOSH list of hazardous drugs in the health care setting:

Please be advised that some text in the accompanying EXCEL spreadsheet is larger than permitted to be visible in the cell allocated by EXCEL. The entire comment is visible in the EXCEL formula bar with a left mouse click on cell E40.

Sincerely yours -

Michael J. Olson, Ph.D., ATS
Director, Occupational Toxicology
Corporate Environment, Health and Safety
GlaxoSmithKline

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Drugs to Review 2006 Docket #NIOOSH-105

Reviewer : Michael J. Olson, Ph.D., ATS

**Affiliation : Occupational Toxicology, Corporate EHS,
GlaxoSmithKline**

<u>Proprietary Name</u>	<u>Established Name</u>	<u>Should this Drug be Included in the NIOSH Hazardous Drugs List ?</u>		<u>Comments</u>
		<u>yes</u>	<u>no</u>	
				Please open cells including text in column E (below). The content of cell E40 exceeds the maximum length for display. However, a left mouse button click on cell E40 will display the entire content in the EXCEL formula bar.

New FDA Drugs and Warnings Fitting NIOSH Criteria For Hazardous Drugs

Abilify	aripiprazole			
Alimta	pemetrexed			
Amevive	alfacept			
Amitiza	lubiprostone			
Apokyn	apomorphine HCl			
Arranon	nelarabine		XX	GSK agrees that the hazards of this substance qualify it for inclusion in the US NIOSH hazardous drugs list.
Avastin	bevacizumab			
Azilect	rasagiline mesylate			
Baraclude	entecavir			
Chantix	varenicline			
Ciolar	clofarabine			
Cordarone	amidarone HCl			
Dacogen	decitabine			
Depacone	valproate Na			
Depakene	valproic acid			
Depakote	divalproex Na			
Depo-Provera**	medroxyprogesterone acetate			
Elidei	pimecrolimus			

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		<table border="1"> <tr> <td><u>yes</u></td> <td><u>no</u></td> </tr> </table>	<u>yes</u>	<u>no</u>	Please open cells including text in column E (below). The content of cell E40 exceeds the maximum length for display. However, a left mouse button click on cell E40 will display the entire content in the EXCEL formula bar.
<u>yes</u>	<u>no</u>				

New FDA Drugs and Warnings Fitting NIOSH Criteria For Hazardous Drugs

Erbix	cetuximab		
Geodon	ziprasidone		
Gleevec	imatinib mesylate		
Hivid	zalcitabine		
Hycamtin	topotecan HCl		Topotecan is included in Appendix A of US NIOSH publication 2004-165 "Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings" and could be omitted from this listing of new drugs for inclusion in the NIOSH hazardous drugs list.
Increlex	mecasermin (rDNA origin)		
Kepivance	palifermin		
Leustatin	cladribine		
Lunesta	eszopiclone		
Lyrca	pregagalin		
Metastron	strontium-89 chloride		
Mycamine	micalfungin sodium		
Myozyme	alglucosidase alfa		
Nexavar	sorafenib		
Orencia	abatacept		

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		yes <input type="checkbox"/> no <input checked="" type="checkbox"/>	Please open cells including text in column E (below). The content of cell E40 exceeds the maximum length for display. However, a left mouse button click on cell E40 will display the entire content in the EXCEL formula bar.

New FDA Drugs and Warnings Fitting NIOSH Criteria For Hazardous Drugs

Paxil	paroxetine HCl	XX	Inclusion of paroxetine-containing products (such as Paxil Tablets) as part of the US NIOSH list of hazardous drugs in healthcare settings is not warranted. NIOSH selection of paroxetine as a potential addition to the list of hazardous drugs is apparently based on a <i>qualitative</i> fit of certain characteristics of paroxetine to the NIOSH criteria for identifying hazardous drugs (e.g., carcinogenic potential and potential for causing adverse reproductive/developmental effects). However, <i>quantitative</i> assessment shows that adverse effects identified in clinical or epidemiological studies (e.g., developmental adverse effects) are associated only with exposure to human medicinal doses. Likewise, dose-response assessment of information from non-clinical (animal) studies shows that adverse outcomes in carcinogenesis and fertility/reproductive toxicology studies are associated only with multiples of the daily maximum human therapeutic dose. In both human and non-clinical (animal) studies adverse outcomes are also dependent on daily repetition of exposure over considerable periods of time. It is also important to
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New FDA Drugs and Warnings Fitting NIOSH Criteria For Hazardous Drugs			
Pentetate Calcium			
Trisodium			
Photofrin	porfimer sodium		
Provera**	medroxyprogesterone acetate		
Quadramet	samarium 153 lexidronam		
Rapamune	sirolimus		
Revlimid	lenalidomide		
Risperdal Consta**	risperdone		
Risperdal**	risperidone		
Rituxan	rituximab		
Rozerem	ramelteon		
Seroquel	quetiapine fumerate		
Spiriva Handihaler	tiotropium bromide		
Sprycel	dasatinib		
Sustiva	efavirenz		
Sutent	sunitinib malate		
Tarceva	erlotinib HCl		
Tindamax	tinidazole		
Tracleer	bosentan		

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New FDA Drugs and Warnings Fitting NIOSH Criteria For Hazardous Drugs

Trileptal	oxcarbazepine		
Tygacil	tigcyciline		
Tysabri	natalizumab		
Velcade	bortizomib		
Vidaza	azacitidine		
Viramune	nevirapine		
Viread	tenofovir		
Vision Blue	trypan blue		
Zolinza	vorinostat		
Zonegran	zonisamide		

New FDA Drugs and Warnings Not Fitting NIOSH Criteria For Hazardous Drugs

Actoplus Met	pioglitazone HCl/ metroformin HCl		
Actos	pioglitazone HCl		
Adderall	amphetamines		
Amphadase**	hyaluronidase		
Apidra	insulin glulisine		
Aptivus	tipranavir		

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New FDA Drugs and Warnings Fitting NIOSH Criteria For Hazardous Drugs

Aranesp	darbepoetin alfa			
Avandaryl	rosiglitazone maleate/ glimepiride			
Avonex	interferon beta 1a			
Betaseron	interferon beta 1b			
Byetta	exenatide			
Campral	acamprosate calcium			
Candidis	caspofungin acetate			
ChiRhoStim	human secretion			
Clozaril	clozapine			
Concerta*	methylphenidate HCl			
Cymbalta	duloxetine HCl			
Daytrana*	methylphenidate HCl			
Dexedrine	dextroamphetamine			
Dilaudid	hydromorphone HCl			
Diovan	valsartan			
Eliaprse	idursulfate			
Elmiron	pentosan polysulfate Na			
Enablex	darifenacin HBr			

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New FDA Drugs and Warnings Fitting NIOSH Criteria For Hazardous Drugs

Epogen**	epoetin alfa			
Eraxis	andulafungin			
Ethylol	amifostine			
Exjade	deferasirox			
Focalin	dexmethphenidate HCl			
Fortovase**	saquinavir mesylate			
Fosrenol	lanthanum carbonate hydrate			
Gabitril	tiagabine			
Herceptin	trastuzumab			
Humira	adalimumab			
Hydase**	hyaluronidase			
Invirase**	saquinavir mesylate			
Iplex	mecasermin rinfabate			
Januvia	sitagliptin phosphate			
Ketek	telithromycin			
Lamictal	lamotrigine			
Levemir	insulin detemir			
Lucentis	ranibizumab			
Lumigan	bimatoprost			

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Should this Drug be Included in the NIOSH Hazardous Drugs List ?
 yes no

Comments
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Macugen	pegaptanib sodium		
Magnevist	gadopentetate dimeglumine		
Metadate*	methylphenidate HCl		
Methylin*	methylphenidate HCl		
Multihance	gabobenate dimeglumine		
Naglazyme	galsulfase		
Nevanac	nepafenac		
Nexium	esomeprazole magnesium		
Noxafil	posaconazole		
NutreStore	L-glutamine		
Omacor	omega-3-acid ethylesters		
Opana	oxymorphone HCl		
Pentetate Zinc			
Trisodium			
Prevacid NapralPAC	lansoprazole; naproxen		
Prezista	darunavir		
Prialt	ziconotide		
Procrit**	epoetin alfa		
Propranolol HCl			

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New FDA Drugs and Warnings Fitting NIOSH Criteria For Hazardous Drugs

Ranexa	ranolazine			
Raptiva	efalizumab			
Remicade	infliximab			
Ritalin*	methylphenidate HCl			
Sanctura	trospium chloride			
Sensipar	cinacalcet HCl			
Serzone	nefazodone HCl			
Strattera	atomoxetine HCl			
Symlin	pramlintide acetate			
Trasylol	aprotinin			
Tyzeka	telbivudine			
Vectibix	panitumumab			
Ventavis	iloprost			
Veregen	kunecatechins			
VESIcare	solifenacin succinate			
Videx	didanosine			
Visudyne	verteporfin			
Vitrase	ovine hyaluronidase			
Wellbutrin**	bupropion HCl			

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New FDA Drugs and Warnings Fitting NIOSH Criteria For Hazardous Drugs

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