

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

From: michael.j.olson@gsk.com
Sent: Wednesday, December 12, 2007 11:58 AM
To: Miller, Diane M. (CDC/NIOSH/EID); MacKenzie, Barbara A. (CDC/NIOSH/DART)
Cc: Connor, Thomas H. (CDC/NIOSH/DART)
Subject: Fw: 105 - HazDrug Update Comments
Attachments: GSKexpanded.xls

Diane, Barbara -

Thank you for your efforts to have the comments which I submitted 20 Sept. 2007 to US NIOSH Docket 105 ("Hazardous Drugs") on behalf of GSK posted to the web space devoted by NIOSH to this topic.

I note however, that the version supplied by Barbara which rectifies a problem with the available cell size in EXCEL was not posted. Instead a facsimile of the original I submitted was reproduced on the web-site. This is not in EXCEL format, cannot be manipulated by readers at the web-site and, therefore does not present the information I submitted in its entirety.

If at all possible, I politely request that the version of the information attached to Barbara's note below please be added to the web-site. The correct EXCEL file contains the description "expanded".

Thank you and Regards -

Mike

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

telephone: 919-483-5239 (GSK internal dial *-703-5239)
 mail address: GlaxoSmithKline, 5 Moore Dr. (CS-1147)
 Research Triangle Park, NC 27709 USA

----- Forwarded by Michael J Olson/CORP/GSK on 12/12/2007 11:49 AM -----

"MacKenzie, Barbara A. (CDC/NIOSH/DART)"
 <bam2@cdc.gov>

To "Miller, Diane M. (CDC/NIOSH/EID)" <dmm2@cdc.gov>
 cc "Connor, Thomas H. (CDC/NIOSH/DART)" <tmc6@cdc.gov>,
 michael.j.olson@gsk.com

05-Dec-2007 09:06

Subject FW: 105 - HazDrug Update Comments

Diane,

A submitted comment from Michael Olson, of GlaxoSmithKline, was inadvertently omitted from the Docket. He sent 2, one in August, and this one in September.

12/20/2007

Can you have this included ?

Barbara MacKenzie

Research Biologist
NIOSH
4676 Columbia Pkwy. MS C-26
Cincinnati, OH 45226
PH 513-533-8132
FAX 513-533-8494
bmackenzie@cdc.gov

From: michael.j.olson@gsk.com [mailto: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

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>
		<input type="checkbox"/> <u>yes</u> <input type="checkbox"/> <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		
Clolar	clofarabine		
Cordarone	amiodarone HCl		
Dacogen	decitabine		
Depacone	valproate Na		
Depakene	valproic acid		
Depakote	divalproex Na		
Depo-Provera**	medroxyprogesterone acetate		
Elidel	pimecrolimus		

Drugs to Review 2006 Docket #NIOHS-105

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Affiliation : Occupational Toxicology, Corporate EHS,
GlaxoSmithKline

Send reviews to: niocindocket@cdc.gov

<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				
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	micafungin sodium			
Myozyme	alglucosidase alfa			
Nexavar	sorafenib			
Orencia	abatacept			

<p>Drugs to Review 2006 Docket #NIOH-105 Reviewer : Michael J. Olson, Ph.D., ATS Affiliation : Occupational Toxicology, Corporate EHS, GlaxoSmithKline</p>		<p>Send reviews to: niocindocket@cdc.gov</p>	
<p><u>Proprietary Name</u></p>	<p><u>Established Name</u></p>	<p><u>Should this Drug be Included in the NIOSH Hazardous Drugs List ?</u> <u>yes</u> <u>no</u></p>	<p><u>Comments</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.</p>
<p>New FDA Drugs and Warnings Fitting NIOSH Criteria For Hazardous Drugs</p>			
<p>Paxil</p>	<p>paroxetine HCl</p>	<p>XX</p>	<p>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.</p>

<p>Drugs to Review 2006 Docket #NIOASH-105 Reviewer : Michael J. Olson, Ph.D., ATS Affiliation : Occupational Toxicology, Corporate EHS, GlaxoSmithKline</p>		<p>Send reviews to: niocindocket@cdc.gov</p>	
<p>Proprietary Name</p>		<p>Established Name</p>	
<p>Should this Drug be Included in the NIOSH Hazardous Drugs List ?</p>		<p>Comments</p>	
<p>yes</p>		<p>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.</p>	
<p>no</p>		<p>It is also important to note that in the healthcare community paroxetine is commonly handled as film-coated tablets which present little risk of exposure. Even crushing the tablet would result in large particles with very little in the way of fines susceptible to air-borne entrainment and inhalation. Nor is substantial percutaneous absorption expected. Paroxetine is also available as an oral suspension but exposure via inhalation or toxicologically significant percutaneous absorption is not expected. Thus, in the context of potential occupational exposure the known hazards of paroxetine are very unlikely to be expressed. The foregoing brief describes a rationale for disqualifying paroxetine as a possible addition to the US NIOSH list of hazardous drugs in health care settings. GSK would be pleased to engage in more detailed communication on NIOSH intent with regard to paroxetine and the list of hazardous drugs in the healthcare setting.</p>	
<p>Pentetate Calcium Trisodium</p>			

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Proprietary Name	Established Name	Should this Drug be Included in the NIOSH Hazardous Drugs List ? yes no	Comments 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			
Photofrin	porfimer sodium		
Provera**	medroxyprogesterone acetate		
Quadramet	samarium 153 lexidronam		
Rapamune	sirolimus		
Revimid	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		
Trileptal	oxcarbazepine		
Tygacil	tigecycline		

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 Affiliation: Occupational Toxicology, Corporate EHS,
 GlaxoSmithKline

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

Comments
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Proprietary Name | Established Name

New FDA Drugs and Warnings Fitting NIOSH Criteria For Hazardous Drugs

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	tipranivir	
Aranesp	darbepoetin alfa	

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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>	

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New FDA Drugs and Warnings Fitting NIOSH Criteria For Hazardous Drugs

Avandaryl	rosiglitazone maleate/ gimepiride			
Avonex	interferon beta 1a			
Beataseron	interferon beta 1b			
Byetta	exenatide			
Campral	acamprosate calcium			
Candidis	caspofungin acetate			
ChiRhoStim	human secretion			
Clozari	clozapine			
Concerta*	methylphenidate HCl			
Cymbalta	duloxetine HCl			
Daytrana*	methylphenidate HCl			
Dexedrine	dextroamphetamine			
Dilaudid	hydromorphone HCl			
Diovan	valsartan			
Elaprase	idursulfate			
Elimiron	pentosan polysulfate Na			
Enablex	darifenacin HBr			
Epogen**	epoetin alfa			

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		<u>Should this Drug be Included in the NIOSH Hazardous Drugs List ?</u> yes no	<u>Comments</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>Proprietary Name</u>	<u>Established Name</u>		
New FDA Drugs and Warnings Fitting NIOSH Criteria For Hazardous Drugs			
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	tellithromycin		
Lamictal	lamotrigine		
Levemir	insulin detemir		
Lucentis	ranibizumab		
Lumigan	bimatoprost		
Macugen	pegaptanib sodium		

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New FDA Drugs and Warnings Fitting NIOSH Criteria For Hazardous Drugs			
Magnevist	gadopentetate dimeglumine		
Metadate*	methylphenidate HCl		
Methylin*	methylphenidate HCl		
Multihance	gadobenate dimeglumine		
Naglazyme	galsulfase		
Nevanac	nepafenac		
Nexium	esomeprazole magnesium		
Noxafil	posaconazole		
NutreStore	L-glutamine		
Omacor	omega-3-acid ethylesters		
Opana	oxycodone HCl		
Pentetate Zinc			
Trisodium			
Prevacid NapralPAC	lansoprazole; naproxen		
Prezista	darunavir		
Prialt	ziconotide		
Procrit**	epoetin alfa		
Propanolol HCl			
Ranexa	ranolazine		

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		<input type="checkbox"/> <u>yes</u> <input type="checkbox"/> <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

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		
Xifaxan	rifaximin		

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<u>Proprietary Name</u>	<u>Established Name</u>	<u>Should this Drug be Included in the NIOSH Hazardous Drugs List ?</u>	<u>Comments</u>
		yes no	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

- Zarontin ethosuximide
- Zinecard dextroazoxane
- Zyban** bupropion HCl
- Zyprexa olanzapine

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

ADDITIONAL COMMENTS