

Dragon, Karen E. (CDC/NIOSH/EID)

From: Christine Swyres [cms8937@bjc.org]
Sent: Monday, September 10, 2007 10:12 AM
To: NIOSH Docket Office (CDC)
Subject: NIOSH review
Attachments: PublicReviewForm2006-05-01-07(1).xls

Please see attached.

Thank you for this opportunity to voice our opinion.

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Drugs to Review 2006 Docket #NIOSH-105

Reviewer :

Affiliation :

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

Proprietary Name Established Name Comments

New FDA Drugs and Warnings Fitting NIOSH Criteria For Hazardous Drugs

Proprietary Name	Established Name	yes	no	Comments
Abilify	aripiprazole		x	Limited exposure risk from formulation
Alimta	pemetrexed	x		Appropriate per mechanism and formulation
Amevive	alfacept		x	
Amitiza	lubiprostone		x	
Apokyn	apomorphine HCl		x	
Arranon	nelarabine	x		Appropriate per mechanism and formulation
Avastin	bevacizumab		x	Risk limited due to molecular size
Azilect	rasagiline mesylate		x	
Baraclude	entecavir		x	
Chantix	varenicline		x	
Clolar	clofarabine	x		
Cordarone	amidarone HCl		x	
Dacogen	decitabine	x		
Depacone	valproate Na		x	
Depakene	valproic acid		x	
Depakote	divalproex Na		x	
Depo-Provera**	medroxyprogesterone acetate	x	x	limited exposure risk with oral medications
Elidel	pimecrolimus	x		
Erbitux	cetuximab	x		Appropriate per mechanism and formulation
Geodon	ziprasidone		x	Limited exposure risk from formulation
Gleevec	imatinib mesylate	x		
Hivid	zalcitibine		x	Limited exposure risk from formulation
Hycamtin	topotecan HCl	x		
Increlex	mecasermin (rDNA origin)	x	x	increased risk of exposure based on dosage formulation
Kepivance	palifermin	x	x	increased risk of exposure based on dosage formulation
Leustatin	cladribine	x		
Lunesta	eszopiclone		x	
Lyrica	pregagalin		x	
Metastron	strontium-89 chloride	x		
Mycamine	micafungin sodium		x	
Myozyme	alglucosidase alfa	x	x	may be appropriate based on mechanism and route of administration
Nexavar	sorafenib	x		
Orencia	abatacept	x		may be appropriate based on previous classification and route of administration
Paxil	paroxetine HCl		x	
Pentetate Calcium Trisodium		x		Appropriate per mechanism
Photofrin	porfimer sodium		x	
Provera**	medroxyprogesterone acetate	x	x	limited exposure risk with oral medications
Quadramet	samarium 153 lexidronam	x		
Rapamune	sirolimus	x		
Revlimid	lenalidomide	x		
Risperdal Consta**	risperdone		x	
Risperdal**	risperidone		x	
Rituxan	rituximab		x	Due to large particle size
Rozerem	ramelteon		x	
Seroquel	quetiapine fumerate		x	
Spiriva Handihaler	tiotropium bromide		x	
Sprycel	dasatinib	x		
Sustiva	efavirenz		x	
Sutent	sunitinib malate	x		
Tarceva	erlotinib HCl	x		

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Proprietary Name

Established Name

yes

no

Comments

New FDA Drugs and Warnings Fitting NIOSH Criteria For Hazardous Drugs

Proprietary Name	Established Name	yes	no	Comments
Tindamax	tinidazole		x	
Tracleer	bosentan	x		
Trileptal	oxcarbazepine		x	
Tygacil	tigcycline		x	
Tysabri	natalizumab			Off market
Velcade	bortizomib	x		? Appropriate per mechanism
Vidaza	azacitidine	x		Appropriate per mechanism
Viramune	nevirapine		x	
Viread	tenofovir		x	
Vision Blue	trypan blue		x	no recommendation at this time
Zolinza	vorinostat	x		
Zonegran	zonisamide		x	

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

Proprietary Name	Established Name	yes	no	Comments
Actoplus Met	pioglitazone HCl/ metroformin HCl		x	
Actos	pioglitazone HCl		x	
Adderall	amphetamines		x	
Amphadase**	hyaluronidase		x	
Apidra	insulin glulisine		x	
Aptivus	tipranivir		x	
Aranesp	darbepoetin alfa		x	
Avandaryl	rosiglitazone maleate/ glimepiride		x	
Avonex	interferon beta 1a		x	
Betaseron	interferon beta 1b		x	
Byetta	exenatide		x	
Campral	acamprosate calcium		x	
Candidis	caspofungin acetate		x	
ChiRhoStim	human secretion		x	
Clozaril	clozapine		x	
Concerta*	methylphenidate HCl		x	
Cymbalta	duloxetine HCl		x	
Daytrana*	methylphenidate HCl		x	
Dexedrine	dextroamphetamine		x	
Dilaudid	hydromorphone HCl		x	
Diovan	valsartan		x	
Elaprase	idursulfate		x	
Elmiron	pentosan polysulfate Na		x	
Enablex	darifenacin HBr		x	
Epogen**	epoetin alfa		x	
Eraxis	andulafungin		x	
Ethiol	amifostine		x	
Exjade	deferasirox		x	
Focalin	dexmethylphenidate HCl		x	
Fortovase**	saquinavir mesylate		x	
Fosrenol	lanthanum carbonate hydrate		x	
Gabitril	tiagabine		x	
Herceptin	trastuzumab		x	
Humira	adalimumab		x	
Hydase**	hyaluronidase		x	
Invirase**	saquinavir mesylate		x	
Iplex	mecasermin rinfabate		x	

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New FDA Drugs and Warnings Fitting NIOSH Criteria For Hazardous Drugs

Januvia	sitagliptin phosphate	x
Ketek	telithromycin	x
Lamictal	lamotrigine	x
Levemir	insulin detemir	x
Lucentis	ranibizumab	
Lumigan	bimatoprost	x
Macugen	pegaptanib sodium	x
Magnevist	gadopentetate dimeglumine	x
Metadate*	methylphenidate HCl	x
Methylin*	methylphenidate HCl	x
Multihance	gadobenate dimeglumine	x
Naglazyme	galsulfase	x
Nevanac	nepafenac	x
Nexium	esomeprazole magnesuim	x
Noxafil	posaconazole	x
NutreStore	L-glutamine	x
Omacor	omega-3-acid ethylesters	x
Opana	oxymorphone HCl	x
Pentetate Zinc Trisodium		x
Prevacid NapralPAC	lansoprazole; naproxen	x
Prezista	darunavir	x
Prialt	ziconotide	x
Procrit**	epoetin alfa	x
Propranolol HCl		x
Ranexa	ranolazine	x
Raptiva	efalizumab	
Remicade	infliximab	
Ritalin*	methylphenidate HCl	x
Sanctura	tropium chloride	x
Sensipar	cinacalcet HCl	x
Serzone	nefazodone HCl	x
Strattera	atomoxetine HCl	x
Symlin	pramlintide acetate	x
Trasylol	aprotinin	x
Tyzeka	telbivudine	x
Vectibix	panitumumab	
Ventavis	iloprost	x
Veregen	kunecatechins	x
VESIcare	solifenacin succinate	x
Videx	didanosine	x
Visudyne	verteporfin	x
Vitrase	ovine hyaluronidase	x
Wellbutrin**	bupropion HCl	x
Xifaxan	rifaximin	x
Zarontin	ethosuximide	x
Zinecard	dextrazoxane	x
Zyban**	bupropion HCl	x
Zyprexa	olanzapine	x

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

ADDITIONAL COMMENTS

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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>
		<u>yes</u>	<u>no</u>	
New FDA Drugs and Warnings Fitting NIOSH Criteria For Hazardous Drugs				