

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

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**From:** Oliver, Mair [Mair.Oliver@astrazeneca.com]  
**Sent:** Wednesday, September 19, 2007 8:28 AM  
**To:** NIOSH Docket Office (CDC)  
**Subject:** 105 - HazDrug Update Comments

**Attachments:** PublicReviewForm2006-05-01-07.xls



PublicReviewForm2  
006-05-01-07....

Dear Sir/Madam,

Please find attached a statement challenging the addition of Seroquel (quetiapine fumarate) to the NIOSH List of Hazardous Drugs. If necessary, you may contact me about this at AstraZeneca, as per details given below.

With kind regards,

Mair Oliver  
Senior Occupational Toxicologist  
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<<PublicReviewForm2006-05-01-07.xls>>

Drugs to Review 2006 Docket #NIOOSH-105

Reviewer :

Affiliation :

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			
Amevive	atacept			
Amitiza	lubiprostone			
Apokyn	apomorphine HCl			
Arranon	nelarabine			
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			
Erbilux	cetuximab			
Geodon	ziprasidone			
Gleevec	imatinib mesylate			
Hivid	zalcitabine			
Hycamtin	topotecan HCl			

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		yes	no	

**New FDA Drugs and Warnings Fitting NIOOSH Criteria For Hazardous Drugs**

Increlex	mecasermin (rDNA origin)			
Keprivance	palifermin			
Leustatin	cladribine			
Lunesta	eszopiclone			
Lyrica	pregabalin			
Metastron	strontium-89 chloride			
Mycamine	micafungin sodium			
Myozyme	alglucosidase alfa			
Nexavar	sorafenib			
Orencia	abatacept			
Paxil	paroxetine HCl			
Pentetate Calcium				
Trisodium				
Photofrin	porfimer sodium			
Provera**	medroxyprogesterone acetate			
Quadramet	samarium 153 lexidronam			
Rapamune	sirolimus			
Revimid	lenalidomide			
Risperdal Consta**	risperdone			
Risperdal**	risperdone			
Rituxan	rituximab			
Rozerem	ramelteon			

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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**

Seroquel	quetiapine fumarate			<p>AstraZeneca argues that this drug does not meet any of the criteria for inclusion when potency and relevance of the toxicological effects seen in animals, to man, are taken into consideration, and should not be added to the NIOSH List of Hazardous Drugs. Justification for this statement, in relation to each of the criteria for which Quetiapine is implicated, is provided below:</p> <p><b>Carcinogenicity:</b> Quetiapine is not considered to represent a carcinogenic risk to humans. Increased incidence of mammary adenocarcinomas observed in female rats were consequent upon prolonged hyperprolactinaemia, which is not seen in man at therapeutic dose levels (50 - 800mg/day). Increased incidence of thyroid follicular cell benign adenomas in male rats and mice was consistent with known rodent-specific mechanisms resulting from enhanced hepatic thyroxine clearance.</p> <p><b>Reproductive Toxicity:</b> Effects related to elevated prolactin levels (marginal reduction in male fertility at 150, but not 50mg/kg/day, and pseudopregnancy, protracted periods of diestrus, increased precoital interval and reduced pregnancy rate a</p>
Spiriva Handihaler	tiotropium bromide		No	
Sprycel	dasatinib			
Sustiva	efavirenz			
Sutent	suunitinib malate			

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**New FDA Drugs and Warnings Fitting NIOSH Criteria For Hazardous Drugs**

Tarceva	erlotinib HCl			
Tindamax	tindazole			
Tracleer	bosentan			
Trileptal	oxcarbazepine			
Tygacil	tigyclyline			
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/ metformin HCl			
Actos	pioglitazone HCl			
Adderall	amphetamines			
Amphadase**	hyaluronidase			
Apidra	insulin glulisine			
Aptivus	tipranavir			
Aranesp	darbepoetin alfa			

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**New FDA Drugs and Warnings Fitting NIOOSH Criteria For Hazardous Drugs**

Avandaryl	rosiglitazone maleate/ glimepiride			
Avonex	interferon beta 1a			
Betaseron	interferon beta 1b			
Byetta	exenatide			
Campral	acamprosate calcium			
Cancidis	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			
Epogen**	epoetin alfa			
Eraxis	andulafungin			
Ethylol	amifostine			
Exjade	deferasirox			
Focalin	dexmethylphenidate HCl			

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**New FDA Drugs and Warnings Fitting NIOOSH Criteria For Hazardous Drugs**

Fortovase**	saguinavir mesylate			
Fosrenol	lanthanum carbonate hydrate			
Gabitril	tiagabine			
Herceptin	trastuzumab			
Humira	adalimumab			
Hydase**	hyaluronidase			
Invirase**	saguinavir mesylate			
Iplex	mecasermin rinfabate			
Januvia	sitagliptin phosphate			
Ketek	telithromycin			
Lamictal	lamotrigine			
Levermir	insulin detemir			
Lucentis	ranibizumab			
Lumigan	bimatoprost			
Macugen	pegaptanib sodium			
Magnevist	gadopentetate dimeglumine			
Metadate*	methylphenidate HCl			
Methylin*	methylphenidate HCl			
Multihance	gadobenate dimeglumine			
Naglazyme	galsulfase			
Nevanac	nepafenac			
Nexium	esomeprazole magnesium			
Noxafil	posaconazole			

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<b>New FDA Drugs and Warnings Fitting NIOOSH Criteria For Hazardous Drugs</b>				
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				
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			



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		yes no	

**New FDA Drugs and Warnings Fitting NIOOSH Criteria For Hazardous Drugs**

Veregen	kunecatechins		
VE Sicare	solifenacin succinate		
Vindex	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**

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