

NEW FDA DRUGS AND WARNINGS FITTING NIOSH CRITERIA FOR HAZARDOUS DRUGS 2006

<u>Proprietary Name</u>	<u>Established Name</u>	NIOSH Hazardous Drugs Criteria					<u>How Supplied</u>
		<u>Cancer</u>	<u>Preg Cat</u>	<u>Repro Tox</u>	<u>Organ Tox</u>	<u>Geno Tox</u>	
Abilify	aripiprazole	+	C	+	+	+	Tablets
Alimta	pemetrexed	NT	D	+	+	+	IV infusion
Amevive	alafacept	+	B	--	+	--	Parenteral injection
Amitiza	lubiprostone	+	C	--		--	Capsules
Apokyn	apomorphine HCl	NT	C	+		+	Dermal injection
Arranon	nelarabine	NT	D	NT	+	+	IV infusion
Avastin	bevacizumab	NT	C	+	+	--	IV infusion
Azilect	rasagiline mesylate	+	C	--		+	Tablets
Baraclude	entecavir	+	C	+/-		+	Tablets, oral suspension
Chantix	varenicline	+/-	C	--		--	Tablets
Clolar	clofarabine	NT	D	+	+/-	+	IV infusion
Cordarone	amidarone HCl	+	D	+	+	--	IV, tablets
Dacogen	decitabine	NT	D	+	+	+	IV infusion
Depacone	valproate Na	+	D	+	+	--	Injection
Depakene	valproic acid	+	D	+	+	--	Tablets
Depakote	divalproex Na	+	D		+	--	Tablets
Depo-Provera**	medroxyprogesterone	+/-	X				IM injection
Elidel	pimecrolimus	+	C	+		--	Cream
Erbix	cetuximab	NT	C	+	+	--	IV infusion
Geodon	ziprasidone	+	C	+	+	+	IM injection
Gleevec	imatinib mesylate	+	D	+	+	+	Tablets
Hivid	zalcitibine	+	C	+	+	+	Tablets
Hycamtin	topotecan HCl	NT	D	+	+	+	IV injection
Increlex	mecasermin (rDNA)	+	C	--		--	Subcutaneous injection
Kepivance	palifermin	NT	C	+			IV injection
Leustatin	cladribine	NT	D	+	+	+	IV infusion
Lunesta	eszopiclone	+	C	+		+	Tablets
Lyrica	pregagalin	+	C	+	+	--	Capsules
Metastron	strontium-89 chloride	+	D	NT		NT	IV injection

NEW FDA DRUGS AND WARNINGS FITTING NIOSH CRITERIA FOR HAZARDOUS DRUGS 2006

<u>Proprietary Name</u>	<u>Established Name</u>	<u>NIOSH Hazardous Drugs Criteria</u>					<u>How Supplied</u>
		<u>Cancer</u>	<u>Preg Cat</u>	<u>Repro Tox</u>	<u>Organ Tox</u>	<u>Geno Tox</u>	
Mycamine	micafungin sodium	NT	C	--	+	--	IV infusion
Myozyme	alglucosidase alfa	NT	B		+	NT	IV infusion
Nexavar	sorafenib	NT	D	+		+/-	Tablets
Orencia	abatacept	+/-	C	--		--	IV infusion
Paxil	paroxetine HCl	+	D	+		--	Tablets
Pentetate Calcium Trisodium		NT	C	+		NT	IV injection
Photofrin	porfimer sodium	NT	C	+	+	+/-	IV injection
Provera**	medroxyprogesterone	+/-	X	+		--	Tablets
Quadramet	samarium 153	+	D	NT		--	IV injection
Rapamune	sirolimus	+	C	+		--	Tablets
Revlimid	lenalidomide	NT	X	+/-	+	--	Capsules
Risperdal**	risperidone	+	C	+	+	--	Tablets, oral solution
Risperdal Consta**	risperdone	+	C	+	+	--	IM injection
Rituxan	rituximab	NT	C	NT	+	NT	IV infusion
Rozerem	ramelteon	+	C	+		+	Tablets
Seroquel	quetiapine fumerate	+	C	+		+/-	Tablets
Spiriva Handihaler	tiotropium bromide	--	C	+		--	Inhalation
Sprycel	dasatinib	NT	D	+		--	Tablets
Sustiva	efavirenz		D				Tablets, capsules
Sutent	sunitinib malate	NT	D	+	+	NT	Capsules
Tarceva	erlotinib HCl	NT	D	+/-		--	Tablets
Tindamax	tinidazole	NT	C	+		+	Tablets
Tracleer	bosentan	+	X	+	+	--	Tablets
Trileptal	oxcarbazepine	+	C	+	+	+	Tablets, oral suspension
Tygacil	tigcyciline	NT	D	+/-		--	IV Infusion
Tysabri	natalizumab	--	C	+	+/-	--	IV Infusion
Velcade	bortizomib	NT	D	+	+	+	IV injection

NEW FDA DRUGS AND WARNINGS FITTING NIOSH CRITERIA FOR HAZARDOUS DRUGS 2006

<u>Proprietary Name</u>	<u>Established Name</u>	<u>NIOSH Hazardous Drugs Criteria</u>					<u>How Supplied</u>
		<u>Cancer</u>	<u>Preg Cat</u>	<u>Repro Tox</u>	<u>Organ Tox</u>	<u>Geno Tox</u>	
Vidaza	azacitidine	+	D	+		+	Subcutaneous injection
Viramune	nevirapine	+	C	+	+	--	Tablets, oral suspension
Viread	tenofovir	+	B	+	+	+	Tablets
Vision Blue	trypan blue	+	C			+	Intraocular injection
Zolinza	vorinostat	NT	D	+		+	Capsules
Zonegran	zonisamide		C	-	+	+	Capsules

Drugs include new FDA approved drugs from 2004-2006; new FDA drug warnings 2006; NIH Hazardous Drugs List

NT = Not Tested; + = characteristic of drug fits NIOSH definition; -- = characteristic of drug does not fit NIOSH definition; +/- = mixed characteristics; * = more than one proprietary name for same drug

Pregnancy Category A

Controlled studies in women fail to demonstrate a risk to the fetus in the first trimester (and there is no evidence of a risk in later trimesters), and the possibility of fetal harm appears remote.

Pregnancy Category B

Either animal-reproduction studies have not demonstrated a fetal risk but there are no controlled studies in pregnant women, or animal-reproduction studies have shown an adverse effect (other than a decrease in fertility) that was not confirmed in controlled studies in women in the first trimester (and there is no evidence of a risk in later trimesters).

Pregnancy Category C

Either studies in animals have revealed adverse effects on the fetus (teratogenic or embryocidal or other) and there are no controlled studies in women, or studies in women and animals are not available. Drugs should be given only if the potential benefit justifies the potential risk to the fetus.

Pregnancy Category D

There is positive evidence of human fetal risk, but the benefits from use in pregnant women may be acceptable despite the risk (e.g., if the drug is needed in a life-threatening situation or for a serious disease for which safer drugs cannot be used or are ineffective).

Pregnancy Category X

Studies in animals or human beings have demonstrated fetal abnormalities, or there is evidence of fetal risk based on human experience or both, and the risk of the use of the drug in pregnant women clearly outweighs any possible benefit. The drug is contraindicated in women who are or may become pregnant.