

## NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2012: Proposed Additions and Deletions to the NIOSH Hazardous Drug List-Charge to Reviewers

The NIOSH Hazardous Drug Committee has reviewed all new FDA drug approvals and new drug warnings for the period since the first update to the list (June 2007) through December 2009. The committee reviewed 48 new drug approvals and 115 drugs with new warnings drugs and identified 45 drugs as potentially hazardous. Of these 45, 7 already have safe handling guidance in the drug package insert. Therefore, 38 drugs were identified for review by the expert panel.

As part of a review of the 2010 list, we are also asking you to reevaluate 5 interferons and one monoclonal antibody.

We are requesting that, as members of the expert panel, you review the list of drugs that NIOSH suggests be added to the list and provide your evaluations and comments on the spreadsheet provided.

You can find Package Inserts and FDA approval information, including reviews for individual drugs at <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>.

NIOSH will review all comments from the expert panel and post a list of proposed additions to the Federal Register for public comment. NIOSH will then make decisions about updating the list based on all comments.

NIOSH has reviewed all comments from the peer reviewers and stakeholders. Reviewers were not asked to provide a consensus opinion and NIOSH made the final determination regarding additions and deletions to the 2010 Hazardous Drug List. The recommendations of the peer reviewers and stakeholders are summarized below.

<b>Proposed Additions</b>			
	<b>Recommendations</b>		
<b>Established Name</b>	<b>Peer Reviewer</b>	<b>Stakeholder</b>	<b>NIOSH</b>
acitretin	Hazardous-unanimous based on teratogenicity	Hazardous-unanimous based on teratogenicity	NIOSH proposes to include on 2012 updated list based on teratogenicity data
ambrisentan	Hazardous-unanimous based on adverse reproductive effects	Hazardous-majority based on adverse reproductive effects	NIOSH proposes to include on 2012 updated list based on adverse reproductive effects
amidarone HCl	Does not meet the criteria of a hazardous drug-majority	Does not meet the criteria of a hazardous drug-majority	NIOSH will not include on 2012 updated list because it does not meet the criteria of a hazardous drug
artemether/lumefantrine	Does not meet the criteria of a hazardous drug-majority	Does not meet the criteria of a hazardous drug-majority	NIOSH will not include on 2012 updated list because it does not meet the criteria of a hazardous drug
atorvastatin	Hazardous-mixed based on	Does not meet the criteria	NIOSH will not include on 2012 updated

	adverse reproductive effects	of a hazardous drug-majority	list because it does not meet the criteria of a hazardous drug
bendamustine HCl	N/A <sup>1</sup>	N/A	NIOSH proposes to include on 2012 updated list based on manufacturer's recommendations for safe handling
bevacizumab	Hazardous-majority based on adverse effect on fertility and teratogenicity	Does not meet the criteria of a hazardous drug - majority	NIOSH will not include on 2012 updated list because it does not meet the criteria of a hazardous drug
cabergoline	Hazardous-majority based on adverse reproductive and fertility effects at low dose and carcinogenicity	Hazardous-majority based on adverse reproductive and fertility effects at low dose and carcinogenicity	NIOSH proposes to include on 2012 updated list based on adverse reproductive and fertility effects at low dose and carcinogenicity
canakinumab	Does not meet the criteria of a hazardous drug - unanimous	Does not meet the criteria of a hazardous drug - majority	NIOSH will not include on 2012 updated list because it does not meet the criteria of a hazardous drug
carbamazepine	Hazardous-majority based on teratogenicity, adverse reproductive effects and carcinogenicity	Hazardous-mixed based on teratogenicity, adverse reproductive effects and carcinogenicity	NIOSH proposes to include on 2012 updated list based on teratogenicity, adverse reproductive effects and carcinogenicity
cetuximab	Hazardous-mixed based on fetal toxicity	Does not meet the criteria of a hazardous drug - majority	NIOSH will not include on 2012 updated list because it does not meet the criteria of a hazardous drug
clorazepate dipotassium	Does not meet the criteria of a hazardous drug-majority	Does not meet the criteria of a hazardous drug-majority	NIOSH will not include on 2012 updated list because it does not meet the criteria of a hazardous drug
clonazepam	Hazardous-majority based on teratogenicity	Hazardous-unanimous based on teratogenicity	NIOSH proposes to include on 2012 updated list based on teratogenicity data
degarelix	N/A	N/A	NIOSH proposes to include on 2012 updated list based on manufacturer's recommendations for safe handling
dronedarone HCl	Hazardous-unanimous based on adverse reproductive and fertility effects at low dose	Hazardous-unanimous based on adverse reproductive and fertility effects at low dose	NIOSH proposes to include on 2012 updated list based on adverse reproductive and fertility effects at low dose
efavirenz	Hazardous-majority based on teratogenicity at low	Hazardous-majority based on teratogenicity at low	NIOSH proposes to include on 2012 updated list based on teratogenicity at low

	dose	dose	dose
ethotoin	Does not meet the criteria of a hazardous drug-majority	Does not meet the criteria of a hazardous drug-majority	NIOSH will not include on 2012 updated list because it does not meet the criteria of a hazardous drug
everolimus	N/A	N/A	NIOSH proposes to include on 2012 updated list based on manufacturer's recommendations for safe handling
ixabepilone	N/A	N/A	NIOSH proposes to include on 2012 updated list based on manufacturer's recommendations for safe handling
lopinavir/ritonavir	Does not meet the criteria of a hazardous drug-majority	Does not meet the criteria of a hazardous drug-majority	NIOSH will not include on 2012 updated list because it does not meet the criteria of a hazardous drug
lovastatin	Does not meet the criteria of a hazardous drug-majority	Does not meet the criteria of a hazardous drug-majority	NIOSH will not include on 2012 updated list because it does not meet the criteria of a hazardous drug
mometasone furoate	Hazardous-unanimous based on teratogenicity and carcinogenicity	Hazardous-majority based on teratogenicity and carcinogenicity	NIOSH proposes to include on 2012 updated list based on teratogenicity and carcinogenicity
mycophenolic acid	Hazardous-unanimous based on adverse reproductive effects and immunosuppression	Hazardous-majority based on adverse reproductive effects and immunosuppression	NIOSH proposes to include on 2012 updated list based on adverse reproductive effects and immunosuppression
nilotinib	Hazardous-unanimous based on adverse developmental and reproductive effects at low doses	Hazardous-majority based on adverse developmental and reproductive effects at low doses	NIOSH proposes to include on 2012 updated list based on adverse developmental and reproductive effects at low doses
oxcarbazepine	Hazardous-mixed based on developmental and fertility effects and carcinogenicity and mutagenicity	Hazardous-majority based on developmental and fertility effects and carcinogenicity and mutagenicity	NIOSH proposes to include on 2012 updated list based on developmental and fertility effects and carcinogenicity and mutagenicity
pamidronate disodium	Hazardous-mixed based on adverse reproductive and fertility effects	Does not meet the criteria of a hazardous drug - majority	NIOSH will not include on 2012 updated list because it does not meet the criteria of a hazardous drug

paroxetine mesylate	Hazardous-mixed based on teratogenicity	Hazardous-mixed based on teratogenicity	NIOSH proposes to include on 2012 updated list based on direct analogy to paroxetine HCl
pazopanib HCl	Hazardous-majority based on adverse effects on fertility and developmental toxicity	Hazardous-majority based on adverse effects on fertility and developmental toxicity	NIOSH proposes to include on 2012 updated list based on adverse effects on fertility and developmental toxicity
phenoxybenzamine HCl	Hazardous-unanimous based on carcinogenicity and mutagenicity	Hazardous-majority based on carcinogenicity and mutagenicity	NIOSH proposes to include on 2012 updated list based carcinogenicity and mutagenicity
pioglitazone HCl	Hazardous-mixed based on animal carcinogenicity	Does not meet the criteria of a hazardous drug - majority	NIOSH will not include on 2012 updated list because it does not meet the criteria of a hazardous drug
pitavastatin Ca	Hazardous-mixed based on liver toxicity and adverse effect developmental effects and organ toxicity	Hazardous-mi liver toxicity and adverse effect developmental effects and organ toxicity	NIOSH proposes to include on 2012 updated list based on liver toxicity and adverse effect developmental effects and organ toxicity
plerixafor	Hazardous-mixed based on adverse reproductive and hematological effects	Hazardous-mixed based on adverse reproductive and hematological effects	NIOSH proposes to include on 2012 updated list based on adverse reproductive and hematological effects
pralatrexate	N/A	N/A	NIOSH proposes to include on 2012 updated list based on manufacturer's recommendations for safe handling
rituximab	Hazardous-mixed based on fetal toxicity	Does not meet the criteria of a hazardous drug - majority	NIOSH will not include on 2012 updated list because it does not meet the criteria of a hazardous drug
romidepsin	N/A	N/A	NIOSH proposes to include on 2012 updated list based on manufacturer's recommendations for safe handling
rosuvastatin Ca	Does not meet the criteria of a hazardous drug-majority	Does not meet the criteria of a hazardous drug-majority	NIOSH will not include on 2012 updated list because it does not meet the criteria of a hazardous drug
rufinamide	Hazardous-unanimous based on adverse reproductive and developmental effects at	Hazardous-majority based on adverse reproductive and developmental effects at low dose	NIOSH proposes to include on 2012 updated list based on adverse reproductive and developmental effects at low dose

	low dose		
simvastatin	Hazardous-mixed based on adverse effects on fertility and teratogenicity	Does not meet the criteria of a hazardous drug-majority	NIOSH proposes to include on 2012 updated list based on adverse effects on fertility and teratogenicity
telavancin HCl	Hazardous-majority based on developmental toxicity	Does not meet the criteria of a hazardous drug-majority	NIOSH proposes to include on 2012 updated list based on developmental toxicity
temsirolimus	N/A	N/A	NIOSH proposes to include on 2012 updated list based on manufacturer's recommendations for safe handling
tetracycline hydrochloride	Hazardous-mixed based on teratogenicity	Hazardous-mixed based on teratogenicity	NIOSH proposes to include on 2012 updated list based teratogenicity
valproic acid/divalproex Na	Hazardous-majority based on teratogenicity	Does not meet the criteria of a hazardous drug-majority	NIOSH proposes to include on 2012 updated list based on teratogenicity
vigabatrin	Hazardous-mixed based on developmental toxicity below therapeutic dose	Hazardous-majority based on developmental toxicity below therapeutic dose	NIOSH proposes to include on 2012 updated list based on developmental toxicity below therapeutic dose
ziprasidone HCl	Hazardous-majority based on genotoxicity, carcinogenicity, teratogenicity and fetal toxicity	Hazardous-majority based on genotoxicity, carcinogenicity, teratogenicity and fetal toxicity	NIOSH proposes to include on 2012 updated list based on genotoxicity, carcinogenicity, teratogenicity and fetal toxicity
zoledronic acid	Hazardous-majority based on teratogenicity at low dose	Hazardous-majority based on teratogenicity at low dose	NIOSH proposes to include on 2012 updated list based on teratogenicity at low dose
<b>Proposed Deletions</b>			
<b>Drugs reclassified as not meeting criteria for a hazardous drug</b>			
alemtuzumab	Hazardous-mixed based on pancytopenia/marrow hypoplasia	Does not meet the criteria of a hazardous drug-majority	NIOSH proposes to remove from the current list because it does not meet the criteria of a hazardous drug
interferon alfa 2a	Hazardous-mixed based on adverse reproductive effects	Does not meet the criteria of a hazardous drug-majority	NIOSH proposes to remove from the current list because it does not meet the criteria of a hazardous drug
interferon alfa 2b	Hazardous-mixed based on adverse reproductive	Does not meet the criteria of a hazardous drug-	NIOSH proposes to remove from the current list because it does not meet the

	effects	majority	criteria of a hazardous drug
interferon alfa n3	Hazardous-majority based on adverse fertility and reproductive effects	Does not meet the criteria of a hazardous drug-majority	NIOSH proposes to remove from the current list because it does not meet the criteria of a hazardous drug
<b>NIOSH proposes to remove these radio-pharmaceuticals from the current list because they are regulated by Nuclear Regulatory Commission, which directs how they are handled</b>			
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tositumomab			
<b>NIOSH proposes to remove these drugs because they are currently not available in the United States</b>			
dienestrol			
interferon alfa n1			
perphosphamide			
piritrexim isethionate			
plicamycin			
prednumustine			
raltitrexed			
trimetrexate glucuronate			
vindesine			

<sup>1</sup>Not Applicable because manufacturer includes drug handling recommendations in drug package insert.