

## **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 of June 2007 through December 2009. The NIOSH Committee reviewed 48 new drug approvals and 115 drugs with new warnings. Forty-five drugs were identified as potentially meeting the NIOSH definition of a hazardous drug. Of these 45 drugs, seven drugs had manufacturer's safe handling guidance in the drug package insert. Therefore, 38 drugs were identified for stakeholder review to determine if these drugs meet the definition of hazardous drug. NIOSH recommends that 24 drugs, in addition to the seven with manufacturers' warnings, meet the definition of hazardous have special handling requirements.

The NIOSH definition of hazardous drug can be found in the 2004 NIOSH Alert Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings in Appendix A. The link to the Alert is <http://www.cdc.gov/niosh/docs/2004-165/>

We are requesting that, as members of the expert panel, you review the list of drugs that NIOSH identified be added to the 2012 Update of the NIOSH List of Antineoplastic and Other Hazardous Drugs. Please provide your evaluations and comments on the provided spreadsheet.

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

As part of the 2012 Update, we are also asking that you re-evaluate 3 interferons and 1 monoclonal antibody that are on the current list. NIOSH is also proposing to remove 2 radiopharmaceutical drugs since their handling is already regulated by the Nuclear Regulatory Commission and 9 drugs that are no longer available in the United States.

NIOSH will review all comments from the expert panel and post a list of proposed additions and deletions to the Federal Register for public comment. After the public comment period, NIOSH will make decisions about updating the list of hazardous drugs taking into account all peer, stakeholder, and public comments.

**Proposed Additions**

<b>Proposed Additions</b>			
	<b>Recommendations</b>		
<b>Established Name</b>	<b>Peer Reviewer</b>	<b>Stakeholder</b>	
		<b>NIOSH</b>	
acitretin	Hazardous-4/4 based on teratogenicity	Hazardous-6/6 based on teratogenicity	NIOSH proposes to include on 2012 updated list based on teratogenicity data
ambrisentan	Hazardous-4/4 based on adverse reproductive effects	Hazardous-5/6 based on adverse reproductive effects	NIOSH proposes to include on 2012 updated list based on adverse reproductive effects
amiodarone HCl	Does not meet the criteria of a hazardous drug-3/4	Does not meet the criteria of a hazardous drug-4/6	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-3/4	Does not meet the criteria of a hazardous drug-4/6	NIOSH will not include on 2012 updated list because it does not meet the criteria of a hazardous drug
atorvastatin	Hazardous-2/4 based on adverse reproductive effects	Does not meet the criteria of a hazardous drug-4/6	NIOSH will not include on 2012 updated list because it does not meet the criteria of a hazardous drug
bendamustine HCl	N/A	N/A	NIOSH proposes to include on 2012 updated list based on manufacturer's recommendations for safe handling
bevacizumab	Hazardous-3/4 based on adverse effect on fertility and teratogenicity	Does not meet the criteria of a hazardous drug -5/6	NIOSH will not include on 2012 updated list because it does not meet the criteria of a hazardous drug
cabergoline	Hazardous-3/4 based on adverse reproductive and fertility effects at low dose and carcinogenicity	Hazardous-5/6 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-4/4	Does not meet the criteria of a hazardous drug -5/6	NIOSH will not include on 2012 updated list because it does not meet the criteria of a hazardous drug
carbamazepine	Hazardous-3/4 based on teratogenicity, adverse reproductive effects and carcinogenicity	Hazardous-3/6 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-2/4 based on fetal toxicity	Does not meet the criteria of a hazardous drug -5/6	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-3/4	Does not meet the criteria of a hazardous drug-5/6	NIOSH will not include on 2012 updated list because it does not meet the criteria of a hazardous drug
clonazepam	Hazardous-3/4 based on teratogenicity	Hazardous-6/6 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
dronedaron HCl	Hazardous- 4/4 based on adverse reproductive and fertility effects at low dose	Hazardous-6/6 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-4/4 based on teratogenicity at low dose	Hazardous-4/6 based on teratogenicity at low dose	NIOSH proposes to include on 2012 updated list based on teratogenicity at low dose
ethotoin	Does not meet the criteria of a hazardous drug-3/4	Does not meet the criteria of a hazardous drug-5/6	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-3/4	Does not meet the criteria of a hazardous drug-4/6	NIOSH will not include on 2012 updated list because it does not meet the criteria of a hazardous drug
lovastatin	Hazardous-2/4 based on adverse developmental effects	Does not meet the criteria of a hazardous drug-4/6	NIOSH will not include on 2012 updated list because it does not meet the criteria of a hazardous drug
mometasone furoate	Hazardous- 4/4 based on teratogenicity and carcinogenicity	Does not meet the criteria of a hazardous drug-4/6	NIOSH proposes to include on 2012 updated list based on teratogenicity and carcinogenicity

mycophenolic acid	Hazardous- 4/4 based on adverse reproductive effects and immunosuppression	Hazardous-5/6 based on adverse reproductive effects and immunosuppression	NIOSH proposes to include on 2012 updated list based on adverse reproductive effects and immunosuppression
nilotinib	Hazardous- 4/4 based on adverse developmental and reproductive effects at low doses	Does not meet the criteria of a hazardous drug-4/6	NIOSH proposes to include on 2012 updated list based on adverse developmental and reproductive effects at low doses
oxcarbazepine	Hazardous-2/4 based on developmental and fertility effects and carcinogenicity and mutagenicity	Hazardous-4/6 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-2/4 based on adverse reproductive and fertility effects	Does not meet the criteria of a hazardous drug -4/6	NIOSH will not include on 2012 updated list because it does not meet the criteria of a hazardous drug
paroxetine mesylate	Hazardous-2/4 based on teratogenicity	Hazardous-3/6 based on teratogenicity	NIOSH proposes to include on 2012 updated list based on direct analogy to paroxetine HCl
pazopanib HCl	Hazardous-3/4 based on adverse effects on fertility and developmental toxicity	Hazardous-5/6 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- 4/4 based on carcinogenicity and mutagenicity	Hazardous-4/6 based on carcinogenicity and mutagenicity	NIOSH proposes to include on 2012 updated list based on carcinogenicity and mutagenicity
pioglitazone HCl	Hazardous-2/4 based on animal carcinogenicity	Does not meet the criteria of a hazardous drug-5/6	NIOSH will not include on 2012 updated list because it does not meet the criteria of a hazardous drug
pitavastatin Ca	Hazardous-2/4 based on liver toxicity and adverse effect developmental effects and organ toxicity	Hazardous-3/6 liver toxicity and adverse effect developmental effects and organ toxicity based on	NIOSH proposes to include on 2012 updated list based on liver toxicity and adverse effect developmental effects and organ toxicity
plerixafor	Hazardous-2/4 based on adverse reproductive and hematological effects	Hazardous-3/6 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	N/A	NIOSH proposes to include on 2012 updated list based on manufacturer's recommendations for safe handling
rituximab	Hazardous-2/4 based on fetal toxicity	Does not meet the criteria of a hazardous drug -5/6	Does not meet the criteria of a hazardous drug -5/6	NIOSH will not include on 2012 updated list because it does not meet the criteria of a hazardous drug
romidepsin	N/A	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-3/4	Does not meet the criteria of a hazardous drug-5/6	Does not meet the criteria of a hazardous drug-5/6	NIOSH will not include on 2012 updated list because it does not meet the criteria of a hazardous drug
rufinamide	Hazardous-4/4 based on adverse reproductive and developmental effects at low dose	Hazardous-5/6 based on adverse reproductive and developmental effects at low dose	Hazardous-5/6 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
simvastatin	Hazardous-2/4 based on adverse effects on fertility and teratogenicity	Does not meet the criteria of a hazardous drug-4/6	Does not meet the criteria of a hazardous drug-4/6	NIOSH proposes to include on 2012 updated list based on adverse effects on fertility and teratogenicity
telavancin HCl	Hazardous-2/4 based on developmental toxicity	Does not meet the criteria of a hazardous drug-4/6	Does not meet the criteria of a hazardous drug-4/6	NIOSH proposes to include on 2012 updated list based on developmental toxicity
temsirolimus	N/A	N/A	N/A	NIOSH proposes to include on 2012 updated list based on manufacturer's recommendations for safe handling
tetracycline hydrochloride	Hazardous-2/4 based on teratogenicity	Hazardous-3/6 based on teratogenicity	Hazardous-3/6 based on teratogenicity	NIOSH proposes to include on 2012 updated list based teratogenicity
valproic acid/divalproex Na	Hazardous-3/4 based on teratogenicity	Does not meet the criteria of a hazardous drug-4/6	Does not meet the criteria of a hazardous drug-4/6	NIOSH proposes to include on 2012 updated list based on teratogenicity
vigabatrin	Hazardous-2/4 based on developmental toxicity below therapeutic dose	Hazardous-4/6 based on developmental toxicity below therapeutic dose	Hazardous-4/6 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-3/4 based on genotoxicity, carcinogenicity, teratogenicity and fetal toxicity	Hazardous-5/6 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-3/4 based on teratogenicity at low dose	Hazardous-5/6 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-2/4 based on pancytopenia/marrow hypoplasia	Does not meet the criteria of a hazardous drug-4/5	NIOSH proposes to remove from the current list because it does not meet the criteria of a hazardous drug
interferon alfa 2a	Hazardous-2/4 based on adverse reproductive effects	Does not meet the criteria of a hazardous drug-3/5	NIOSH proposes to remove from the current list because it does not meet the criteria of a hazardous drug
interferon alfa 2b	Hazardous-3/4 based on adverse reproductive effects	Does not meet the criteria of a hazardous drug-4/5	NIOSH proposes to remove from the current list because it does not meet the criteria of a hazardous drug
interferon alfa n3	Hazardous-2/3 based on adverse fertility and reproductive effects	Does not meet the criteria of a hazardous drug-3/5	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</b>			
ibritumomab tiuxetan	Remove-4/4	Remove 6/6	NIOSH proposes to remove from the current list because it is regulated by the Nuclear Regulatory Agency
tositumomab	Remove-4/4	Remove 6/6	NIOSH proposes to remove from the current list because it is regulated by the Nuclear Regulatory Agency
<b>NIOSH proposes to remove these drugs from the current list</b>			
dienestrol	Remove-4/4	Remove 6/6	NIOSH proposes to remove from the current list because it is not available in the United States
interferon alfa n1	Remove-4/4	Remove 6/6	NIOSH proposes to remove from the current list because it is not available in the United States

perphosphamide	Remove-4/4	Remove 6/6	NIOSH proposes to remove from the current list because it is not available in the United States
piritrexim isethionate	Remove-4/4	Remove 6/6	NIOSH proposes to remove from the current list because it is not available in the United States
plicamycin	Remove-4/4	Remove 6/6	NIOSH proposes to remove from the current list because it is not available in the United States
prednumstine	Remove-4/4	Remove 6/6	NIOSH proposes to remove from the current list because it is not available in the United States
raltitrexed	Remove-4/4	Remove 6/6	NIOSH proposes to remove from the current list because it is not available in the United States
trimetrexate glucuronate	Remove-4/4	Remove 6/6	NIOSH proposes to remove from the current list because it is not available in the United States
vindesine	Remove-4/4	Remove 6/6	NIOSH proposes to remove from the current list because it is not available in the United States

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