

Table 4, below, is excerpted from the Federal Register notice entitled *NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings: Proposed Additions to the NIOSH Hazardous Drug List 2018*, 83 Fed. Reg. 6563 (Feb. 14, 2018). Public comments are requested on the drugs in Table 4, which are proposed by NIOSH to be added to the List of Antineoplastic and Other Hazardous Drugs, as well as all of the drugs identified in the Federal Register notice that were screened and evaluated which are not being proposed for placement on the List.

Comments may be submitted, identified by docket numbers CDC-2018-0004 and NIOSH-233-B, by either of the following two methods:

- Federal eRulemaking Portal: www.regulations.gov Follow the instructions for submitting comments to docket CDC-2018-0004.
- Mail: NIOSH Docket Office, Robert A. Taft Laboratories, MS-C34, 1090 Tusculum Avenue, Cincinnati, OH 45226-1998.

Instructions: All information received in response to this request for comment must include the agency name (National Institute for Occupational Safety and Health, CDC) and the docket numbers (CDC-2018-0004; NIOSH-233-B). All relevant comments received will be posted without change to www.regulations.gov, including any personal information provided.

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Table 4. Drugs Proposed for Placement on the NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings (Category 1 -- Special Handling Information & Category 5 -- Drug Meets the NIOSH Definition of Hazardous Drug)

Generic Drug Name		
Bevacizumab	Formulation ^aIV	Rationale for Proposing Placement on the List
	Dosage.....5-15 mg/kg	<i>Reproductive toxicity and Teratogenicity or other developmental toxicity: ovarian failure in patients in clinical trials, embryo-fetal toxicity in rabbits</i>
	AHFS Class ^b Antineoplastic	Package Insert
	New Drug ^cYes	https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=939b5d1f-9fb2-4499-80ef-0607aa6b114e
Special Handling Information ^dNo	2018 Update Table No. ^e1	
Blinatumomab	Formulation.....IV	Rationale for Proposing Placement on the List
	Dosage.....9 mcg/day	<i>Organ toxicity at low doses: neurotoxicity at low doses in patients in clinical studies</i>
	AHFS Class.....Antineoplastic	Package Insert
	New Drug.....Yes	https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=38b482a8-960b-4591-9857-5031ecb830aa
Special Handling Information.....No	2018 Update Table No.....1	
Botulinum toxins, all forms including abobotulinimtoxinA and onabotulinumtoxinA	Formulation.....IM	Rationale for Proposing Placement on the List
	Dosage.....1-1000 units	<i>Organ toxicity at low doses and Teratogenicity or other developmental toxicity: spread of toxin effects, reductions in fetal body weight and decreased fetal skeletal ossification at human dose</i>
	AHFS Class.....Neurotoxin	Package Insert
	New Drug.....No	https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=all&query=botulinum+toxin+type+A&pagesize=200&page=1 *
Special Handling Information.....No	2018 Update Table No.....2	
Ceritinib	Formulation.....Capsule	Rationale for Proposing Placement on the List
	Dosage.....750 mg	<i>Teratogenicity or other developmental toxicity: embryo-fetal toxicity at low doses in rats and rabbits</i>
	AHFS Class.....Antineoplastic	Package Insert
New Drug.....Yes		

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	Special Handling InformationNo 2018 Update Table No.1	https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=fff5d805-4ffd-4e8e-8e63-6f129697563e
Clobazam	FormulationTablet, oral suspension Dosage20 mg/kg AHFS ClassAntiepileptic New DrugNo Special Handling InformationNo 2018 Update Table No.3	Rationale for Proposing Placement on the List <i>Reproductive toxicity and Teratogenicity or other developmental toxicity: embryo-fetal mortality and other harm at low doses in rats and rabbits, present in human breast milk</i>
		Package Insert https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=de03bd69-2dca-459c-93b4-541fd3e9571c
Cobimetinib	FormulationTablet Dosage60 mg AHFS ClassAntineoplastic New DrugYes Special Handling InformationNo 2018 Update Table No.1	Rationale for Proposing Placement on the List <i>Reproductive toxicity and Teratogenicity or other developmental toxicity: increased post-implantation loss, including total litter loss in rats at low doses; post-implantation loss and fetal malformations in humans</i>
		Package Insert https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=c387579e-cee0-4334-bd1e-73f93ac1bde6
Darbepoetin alfa	FormulationIV, SQ Dosage0.45-2.25 mcg/kg AHFS ClassErythropoiesis stimulator New DrugNo Special Handling InformationNo 2018 Update Table No.2	Rationale for Proposing Placement on the List <i>Carcinogenicity: progression or recurrence of several cancers in studies of patients with cancer; reduced body weight in offspring at low doses in rats and rabbits</i>
		Package Insert https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=0fd36cb9-c4f6-4167-93c9-8530865db3f9
Dihydroergotamine	FormulationIV, IM, SQ, nasal spray Dosage1 mg AHFS Class5HT receptor binder New DrugNo	Rationale for Proposing Placement on the List <i>Reproductive toxicity: oxytocic properties at low doses in humans</i>
		Package Insert

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	Special Handling InformationNo 2018 Update Table No3	https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=all&query=Dihydroergotamine *
Exenatide	FormulationSQ Dosage2 mg/week AHFS ClassAntidiabetic New DrugNo Special Handling InformationNo 2018 Update Table No2	Rationale for Proposing Placement on the List <i>Carcinogenicity and Teratogenicity or other developmental toxicity: thyroid C-cell tumors in rat studies; adverse fetal effects in rats and mice</i>
		Package Insert https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=all&query=Exenatide *
Inotuzumab ozogamicin	FormulationIV Dosage0.5-0.8 mg/m ² AHFS ClassAntineoplastic New DrugYes Special Handling InformationYes 2018 Update Table No1	Rationale for Proposing Placement on the List <i>Manufacturer special handling information: drug is cytotoxic, users should follow applicable OSHA handling and disposal procedures</i>
		Package Insert https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=cc7014b1-c775-411d-b374-8113248b4077
Interferon beta-1b	FormulationSQ Dosage0.25 mg AHFS ClassImmune modulator New DrugNo Special Handling InformationNo 2018 Update Table No2	Rationale for Proposing Placement on the List <i>Reproductive toxicity: spontaneous abortions in human clinical trials</i>
		Package Insert https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=all&query=Interferon+beta-1b
Isotretinoin	FormulationCapsule Dosage0.5-1 mg/kg AHFS ClassRetinoid New DrugNo Special Handling InformationNo 2018 Update Table No3	Rationale for Proposing Placement on the List <i>Teratogenicity or other developmental toxicity: severe fetal malformations at any dose in humans</i>
		Package Insert https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=all&query=Isotretinoin *
Ivabradine	FormulationTablet	Rationale for Proposing Placement on the List

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	Dosage5-7.5 mg AHFS ClassHCN blocker New DrugYes Special Handling InformationNo 2018 Update Table No.3	<i>Teratogenicity or other developmental toxicity:</i> embryo-fetal toxicity and teratogenicity at low doses in rats Package Insert https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=92018a65-38f6-45f7-91d4-a34921b81d0d
Lenvatinib	FormulationCapsule Dosage24 mg AHFS ClassAntineoplastic New DrugYes Special Handling InformationNo 2018 Update Table No.1	Rationale for Proposing Placement on the List <i>Teratogenicity or other developmental toxicity:</i> embryo-fetal toxicity at low doses in rats and rabbits; abortifacient in rabbits at low doses Package Insert https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=f4bedd21-efde-44c6-9d9c-b48b78d7ed1e
Miltefosine	FormulationCapsule Dosage50 mg AHFS ClassAntibiotic New DrugYes Special Handling InformationNo 2018 Update Table No.3	Rationale for Proposing Placement on the List <i>Teratogenicity or other developmental toxicity:</i> fetal death and teratogenicity at low doses in rats and rabbits Package Insert https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=all&query=Miltefosine *
Olaparib	FormulationCapsule Dosage400 mg AHFS ClassAntineoplastic New DrugYes Special Handling InformationNo 2018 Update Table No.1	Rationale for Proposing Placement on the List <i>Carcinogenicity and Teratogenicity or other developmental toxicity:</i> myelodysplastic syndrome/acute myeloid leukemia in patients in clinical studies; embryo-fetal toxicity, post implantation loss, malformations at low doses in rats Package Insert https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=5e31a6a9-864f-4aba-8085-37ee1ddcd499
Osimertinib	FormulationTablet Dosage80 mg AHFS ClassAntineoplastic	Rationale for Proposing Placement on the List <i>Teratogenicity or other developmental toxicity:</i> embryo-fetal toxicity and lethality and reduced growth in offspring in rats

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	New DrugYes Special Handling InformationNo 2018 Update Table No1	Package Insert https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=5e81b4a7-b971-45e1-9c31-29cea8c87ce7
Sonidegib	FormulationCapsule Dosage200 mg AHFS ClassAntineoplastic New DrugYes Special Handling InformationNo 2018 Update Table No1	Rationale for Proposing Placement on the List <i>Reproductive toxicity and Teratogenicity or other developmental toxicity: embryo-fetal toxicity, teratogenesis, and spontaneous abortions at low doses in rabbits</i> Package Insert https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=all&query=Sonidegib *
Trabectedin	FormulationIV Dosage1.5 mg/m ² AHFS ClassAntineoplastic New DrugYes Special Handling InformationYes 2018 Update Table No1	Rationale for Proposing Placement on the List <i>Manufacturer special handling information: drug is cytotoxic, users should follow applicable OSHA handling and disposal procedures</i> Package Insert https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=472bd78e-be17-4b9d-90f4-9482c3aec9ff
Trastuzumab	FormulationIV Dosage2-6 mg/kg AHFS ClassAntineoplastic New DrugNo Special Handling InformationNo 2018 Update Table No1	Rationale for Proposing Placement on the List <i>Organ toxicity at low doses and Teratogenicity or other developmental toxicity: cardiac and pulmonary toxicity in patients; malformations and neonatal death in patients</i> Package Insert https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=492db2-077e-4064-bff3-372d6af0a7a2
Triazolam	FormulationTablet Dosage0.25 mg AHFS ClassHypnotic New DrugNo Special Handling InformationNo 2018 Update Table No3	Rationale for Proposing Placement on the List <i>Mimics existing drugs determined hazardous by exhibiting teratogenicity or other developmental toxicity: drug is a benzodiazepine, a class known to cause congenital malformations and cross placenta in patients</i> Package Insert

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		https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=all&query=triazolam&pagesize=200&page=1
Urofollitropin	FormulationIM, SQ	Rationale for Proposing Placement on the List <i>Teratogenicity or other developmental toxicity:</i> drug is known to cause fetal harm in patients
	Dosage150-450 IU	
	AHFS ClassOvulation stimulator	Package Insert
	New DrugNo	https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=9bb87daf-d156-504e-adaf-4c21383f8d16
Special Handling InformationNo		
2018 Update Table No3		

- ^a IM = intramuscular, IV = intravenous, SQ = subcutaneous
- ^b AHFS (American Hospital Formulary Service) Pharmacologic-Therapeutic Classification system.
- ^c FDA-approved drug (January 2014-December 2015).
- ^d Manufacturer's package insert statement cautioning that the drug should be handled as hazardous.
- ^e The final *NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings* is subdivided into three tables: Table 1 contains antineoplastic drugs, including those with special handling information provided by the manufacturer; Table 2 contains non-antineoplastic drugs, including those with special handling information; and Table 3 contains non-antineoplastic drugs that primarily have adverse reproductive and/or teratogenic effects.
- * Individual package inserts from multiple manufacturers were reviewed.

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