Summary of Replies to Docket 190				
Name	**Company/ Organization**	**Drugs**	**Comments**	**Replies to Comments**
Brian Krause	State of VA, Central Virginia Training Center	Clonazepam, Simvastatin, Tetracycline, Ziprasidone	We have many patients who take medications by gastric tube or that requite medications to be crushed. Why are these drugs put on list and not other similar drugs in same class?	Simvastatin will not be listed as a hazardous drug in this update. Clonazepam, Tetracycline, and Ziprasidone meet the definition of a hazardous drug. As the number of tablets that are crushed increases, potential exposure to the worker also increases and therefore they should be following recommended precautions.
Elisa Burton	State of VA, Central Virginia Training Center	Clonazepam, Simvastatin, Tetracycline, Ziprasidone	We have many patients who take medications by gastric tube or that requite medications to be crushed. Why are these drugs put on list and not other similar drug in same class?	Simvastatin will not be listed as a hazardous drug in this update. Clonazepam, Tetracycline, and Ziprasidone meet the definition of a hazardous drug. As the number of tablets that are crushed increases, potential exposure to the worker also increases and therefore they should be following recommended precautions.
Kimberly Lipscomb	State of VA, Central Virginia Training Center	Clonazepam, Simvastatin, Tetracycline, Ziprasidone	We have many patients who take medications by gastric tube or that requite medications to be crushed. Why are these drugs put on list and not other similar drugs in same class?	Simvastatin will not be listed as a hazardous drug in this update. Clonazepam, Tetracycline, and Ziprasidone meet the definition of a hazardous drug. As the number of tablets that are crushed increases, potential exposure to the worker also increases and therefore they should be following recommended precautions.
Stephen Eisenstein	State of VA, Central Virginia Training Center	Clonazepam, Simvastatin, Tetracycline, Ziprasidone	We have many patients who take medications by gastric tube or that requite medications to be crushed. Why are these drugs put on list and not other similar drugs in same class?	Simvastatin will not be listed as a hazardous drug in this update. Clonazepam, Tetracycline, and Ziprasidone meet the definition of a hazardous drug. As the number of tablets that are crushed increases, potential exposure to the worker

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Not given	State of VA, Central Virginia Training Center	Clonazepam, Simvastatin, Tetracycline, Ziprasidone	We have many patients who take medications by gastric tube or that requite medications to be crushed. Why are these drugs put on list and not other similar drugs in same class?	Simvastatin will not be listed as a hazardous drug in this update. Clonazepam, Tetracycline, and Ziprasidone meet the definition of a hazardous drug. As the number of tablets that are crushed increases, potential exposure to the worker also increases and therefore they should be following recommended precautions.
Dorothy Rogers	State of VA, Central Virginia Training Center	Tegretol	We have many patients who take medications by gastric tube or that requite medications to be crushed. What is the specific reason why is it listed?	This drug has demonstrated teratogenic, carcinogenic and reproductive effects. As the number of tablets that are crushed increases, potential exposure to the worker also increases and therefore they should be following recommended precautions.
Nadine Badry	BC Cancer	No specific drugs	Appears to be inconsistency in how NIOSH applies criteria. Need clarification on how they are applied. Explain what constitutes a positive result. What is the role of stakeholders in process? Explain stakeholder vs. peer reviewer roles, especially when conclusions differ. How does one interpret the status of a drug not on the list? Will NIOSH publish list of reviewed drugs that are non-hazardous drugs?	NIOSH first reviews information in the drug package inserts and makes a preliminary assessment of the drug's hazard according to the NIOSH definition of a hazardous drug. The stakeholders and peer reviewers complete their own reviews. NIOSH meets with the stakeholders and peer reviewers and discusses each drug. Each reviewer submits their recommendations. NIOSH then completes a second review of all reviewers' comments and makes a decision for publication in the Federal Register. Following the public comment period, NIOSH makes its final recommendations to the Director's Office based on all available information. Once approved, the list is published in the Federal Register.

			The list is used outside US and previous listing should not be removed because that may still be available in other countries. Why remove drugs that have been assessed previously?	It is not possible for NIOSH to review every drug that is in use in the U.S. Any new drug approved by FDA since 2004 has been reviewed by NIOSH. Drugs that were on the market before 2004 are only reviewed if a new warning has been issued by FDA. Drugs approved after 2009 are currently being reviewed by NIOSH.
			Radiopharmaceuticals should remain on the list with an indication that they have additional recommendations.	The American Pharmaceutical Association requested that NIOSH remove the radiopharmaceuticals from its list because these drugs are regulated by the Nuclear regulatory Agency and require special handling. The non-radioactive form of Pentatate Calcium Trisodium will remain on the list due to other characteristics.
			Details for reclassification as non-hazardous should be given.	The original NIOSH list utilized lists from four different institutions and they were not given a rigorous evaluation by NIOSH at the time. Based on comments received by NIOSH some drugs were re-evaluated and found not to fit the definition of a hazardous drug.
Mario de Lemos	BC Cancer	Alemtuzumab, Bevacizumab, Cetuximab, Interferon alfa 2b, Nilotinib, Pamidronate, Rituximab	Provide complete list of drugs reviewed so that non-hazardous drugs can be identified more easily.	The original number of drugs that NIOSH reviews each time is considerably long. Any drug approved by FDA since 2004 has been reviewed by NIOSH. Drugs that were on the market before 2004 are only reviewed if a new warning has been issued by FDA. Drugs approved after 2009 are currently being

				reviewed by NIOSH.
			If the review methodology is the same for both, why separate stakeholder and peer reviewer comments?	NIOSH is required to utilize both stakeholders and peer reviewers. Stakeholders and peer reviewers may take a different view of what is hazardous and what is not. NIOSH attempts to obtain different points of view in order to evaluate the entire possible spectrum of opinions.
			Who were the stakeholders and did they include reps for drug handlers?	The stakeholders are attached. Several representatives for the end users were among the stakeholders.
			How are recommendations made when stakeholder and peer reviewer comments differ?	A NIOSH committee re-evaluates all the available data and makes a determination on that information.
Linda McElhiney (1)	Indiana University Health	Benzodiazepines, anticonvulsants, statins, SSRIs, antiarrhythmic, tetracycline, antipsychotics	These drugs should not be on the list. Worker would need to ingest large doses. Critical of government actions.	The statins will not be listed as hazardous in this update. The dose required to produce an effect is taken into consideration when the drugs are reviewed.
Linda McElhiney (2)	Indiana University Health	Carbamazepine, clonazepam, paroxetine, pitavastin, simvastatin, rufinamide, tetracycline, valproic acid, viabatrin, ziprasidone	Should have a separate category for these drugs. Critical of government actions.	The statins and rufinamide will not be listed as hazardous in this update. NIOSH understands that some drugs are more hazardous than others. However, NIOSH believes that having multiple categories of hazardous drugs can be confusing to the end users and recommends a more universal/standard precautions approach to safe handling.
Shannon	Not given	Anticonvulsants,	These should not be listed. Critical	The statins will not be listed as hazardous in

MMcKinney		anticoagulants, antibiotics, vitamins	of government actions.	this update. The anticonvulsant, antibiotic and vitamin that are listed meet the NIOSH criteria for a hazardous drug.
Jeff Brittain	Pharmacist	Simvastatin	Simvastatin is a safe drug and should not be listed. Listing it destroys credibility of the list. Questions our source of information.	The statins will not be listed as hazardous in this update.
Thomas Menighhan	APhA	Radiopharmaceuticals Teteracycline, statins, benzodiazepines, SSRIs	Supports NIOSH's decision to remove radiopharmaceuticals from list because they are regulated by NRC. Encourages NIOSH to exclude radiopharmaceuticals unless they have other properties that make them hazardous. Reconsider listing as hazardous due to undue burden on healthcare providers and not meeting the threshold for exposure risk.	These radiopharmaceuticals will be removed from the NIOSH list. The non-radioactive form of Pentatate Calcium Trisodium will remain on the list The statins will not be listed as hazardous in this update. The remaining drugs meet the NIOSH criteria for a hazardous drug.
Clyde Cole	GE Healthcare	Ibritumomab tiuxetan, Tositumomab Pentatate Calcium Trisodium	Support removal of these radiopharmaceuticals. Support removal of radioactive form (Tc-99m)	These radiopharmaceuticals will be removed from the NIOSH list. The non-radioactive form of Pentatate Calcium Trisodium will remain on the list with a possible footnote related to the radioactive form
James Ponto	University of Iowa	Ibritumomab tiuxetan, Tositumomab Pentatate Calcium Trisodium	Support removal of these radiopharmaceuticals. Footnote that HD listing is only for the non-radioactive compound, not	These radiopharmaceuticals will be removed from the NIOSH list. The non-radioactive form of Pentatate Calcium Trisodium will remain on the list

			radioactive form (Tc-99m)	with a possible footnote related to the radioactive form
Jade Folstrom	Eisenhower Medical Center	Bevacizumab, Natalizumab, Tocilizumab, Abacept	Should these immunosuppressant drugs be evaluated by NIOSH?	Bevacizumab, Natalizumab have been reviewed previously and were not listed as hazardous based on the NIOSH definition. Abatacept was reviewed previously and was not listed as hazardous. Based on a recent FDA warning, it will be reviewed again for the next update. Tocilizumab was approved after 2009 and is currently being reviewed for the next update.
Not given	Televance	Televancin (Vibativ)	Recommend removal of Televancin from list. Developmental effects only seen at very high doses (500-700 mg/day) in three species. Not possible to take up high dose in occupational setting. (considerable supporting material provided)	NIOSH has reviewed the information provided by the manufacture, but will list Televancin as hazardous.
Christopher Topoleski	ASHP	Paroxetine, Bismuth biskalcitrate/metronidazole/tetracycline HCl, Valproic acid Ambrisentan, Carbamazepine, Paroxetine, Pitavastatin, Phenoxybenzamine, Plerixafor, Nilotinib, Simvastatin, Valproic acid Monoclonal antibodies	Recommended classification based on risk for selected or pre-disposed populations. Only those workers at risk (reproductive) need be protected, not all workers. Supporting data are variable and at supra-therapeutic doses. Film-coated tablets pose little risk. A formal risk assessment may be needed for these drugs. May have been listed based on AHFS classification. Too large to be absorbed.	The statins will not be listed as hazardous in this update. The remaining drugs meet the criteria of a hazardous drug as defined by NIOSH. The monoclonal antibodies were originally listed partially on their AHFS classification and partially due to their being included on

				the four lists NIOSH adopted for the original in 2004. Most of the monoclonal antibodies have been removed from the list.
William McGrath	BMS	Sustiva	Recommend removal of Sustiva from list. Does not meet definition of a hazardous drug. High doses required for developmental toxicity. (supporting material)	Based on additional information, Efavirenz (Sustiva) will not be listed as hazardous.
Nancy Bower	Eisai, Inc	Rufinamide	Recommend removal of Rufinamide from list. Reproductive and developmental toxicity secondary to maternal toxicity. (considerable supporting evidence provided)	Based on additional information provided by the manufacturer, Rufinamide will not be listed as hazardous.