

**Dragon, Karen E. (CDC/NIOSH/EID)**

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**From:** Justine Coffey [JCoffey@ashp.org]  
**Sent:** Wednesday, June 24, 2009 2:39 PM  
**To:** NIOSH Docket Office (CDC)  
**Subject:** Re: Comment re: Docket Number 105-A  
**Attachments:** NIOSH Comments Final.doc

Hello -

I am attaching ASHP's comments in Word format, in addition to the PDF I just sent.

Thank you again,  
Justine

Justine Coffey, JD, LLM  
Director, Federal Regulatory Affairs  
American Society of Health-System Pharmacists  
Government Affairs Division  
7272 Wisconsin Avenue  
Bethesda, MD 20814  
Phone: 301-664-8702  
Fax: 301-634-5802

Justine Coffey/Ashp

06/24/2009 02:31 PM

To: nioshdocket@cdc.gov  
cc  
Subject: Comment re: Docket Number 105-A

Hello -

Attached please find the American Society of Health-System Pharmacists' comments regarding updating the list of hazardous drugs for the NIOSH alert: Additions and deletions to the NIOSH hazardous drug list.

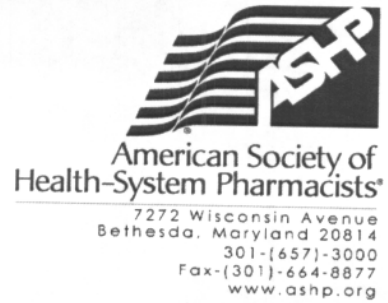
Please feel free to contact me if you have any questions or concerns regarding our submission.

Thank you,  
Justine

[attachment "NIOSH Comments Final.pdf" deleted by Justine Coffey/Ashp]

Justine Coffey, JD, LLM  
Director, Federal Regulatory Affairs  
American Society of Health-System Pharmacists  
Government Affairs Division  
7272 Wisconsin Avenue  
Bethesda, MD 20814  
Phone: 301-664-8702  
Fax: 301-634-5802

6/25/2009



June 24, 2009

NIOSH Docket Office  
Robert A. Taft Laboratories  
MS-C34  
4676 Columbia Parkway  
Cincinnati, Ohio 45226

**Re: NIOSH Docket No. 105-A – Updating the List of Hazardous Drugs for the NIOSH Alert: Additions and Deletions to the NIOSH Hazardous Drug List**

Dear Sir/Madam:

The American Society of Health-System Pharmacists (ASHP) is pleased to submit written comments pertaining to updating the list of hazardous drugs for the National Institute for Occupational Safety and Health (NIOSH) alert. For more than 60 years, ASHP has helped pharmacists who practice in hospitals and health systems improve medication use and enhance patient safety. The Society's 35,000 members include pharmacists and pharmacy technicians who practice in inpatient, outpatient, home-care, and long-term-care settings, as well as pharmacy students. Pharmacists in hospitals and health systems are experts in medication use who serve on interdisciplinary patient-care teams. They work with physicians, nurses, and other health-care professionals to ensure that medicines are used safely and effectively.

As a member of the reviewer panel established by NIOSH to assist in the hazardous drug list update, ASHP commends NIOSH for removing a number of drugs from the initial proposed list, including all but eight of the forty-three drugs the Society recommended for deletion. However, based on the following, previously communicated considerations, we urge NIOSH to re-evaluate the decision to include the agents listed below on the hazardous drug list.

**Classification based on risk for selected or pre-disposed populations**

ASHP questions the need for hazard precautions for health care workers who are not at risk for reproductive hazards or others who do not have predisposing conditions that may increase their susceptibility to harm from the drug. These drugs include: alefacept, bosentan, dasatinib, medroxyprogesterone acetate, paroxetine, and risperidone. In light of the resource-intensive activities associated with hazard management, only those individuals who may be at risk should be protected from these drugs, rather than all

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health care workers. This approach is consistent with how other drugs with reproductive risks, such as finasteride, are currently managed.

**Classification based on inherent toxicity, without consideration of drug formulation, likelihood of occupational exposure, or association of occupational exposure with toxicity**

There are strong study data supporting the hazardous effects of rasagiline, sirolimus, medroxyprogesterone, and paroxetine in vitro or in animals with therapeutic or supra-therapeutic dosing. However, additional discussion is warranted for these drugs since no harm is anticipated from the lesser extent of occupational exposure. Paroxetine tablets are film-coated, which greatly reduces powdering. Exposure to sirolimus from crushing tablets is not a factor because this agent is available in liquid form. Workers can be protected during manipulations of the liquid by universal precautions. While rasagiline is indicated for Parkinson's disease, its mechanism of action is inhibition of monoamine oxidase. Therefore, its use will be restricted to a limited population of carefully selected Parkinson's patients due to a number of contraindications, drug interactions, dietary restrictions, and other precautions for use. This agent's low daily dose coupled with infrequent use limits opportunities for health care worker exposure. The risk of occupational exposure to parenteral medroxyprogesterone is significantly reduced by use of aseptic technique recommended for manipulation and administration of injections.

At present, there is no evidence to support the assertion that limited exposure to these agents in the workplace presents a health risk to the health care practitioner. A formal risk assessment that includes the extent of workplace and worker contamination (e.g., air and surface contamination, dermal contact and skin absorption, and urine testing) may be warranted. It is premature to designate these drugs as hazardous before such evidence is available. This is especially pertinent with intact dosage formulations.

The Society appreciates this opportunity to present its written comments on the NIOSH List of Hazardous Drugs. Feel free to contact Bona Benjamin, B.S. Pharm., Director, Medication-Use Quality Improvement, if you have any questions regarding our comments. She can be reached by telephone at 301-664-8796, or by e-mail at [bbenjamin@ashp.org](mailto:bbenjamin@ashp.org).

Sincerely,



Justine Coffey, JD, LLM  
Director, Federal Regulatory Affairs