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

From: Hansen, Jason [JHansen@APHANET.ORG]

Sent: Monday, October 03, 2011 5:46 PM

To: NIOSH Docket Office (CDC)

Subject: APhA comments on Hazardous Drug List Proposed Revisions - Docket Number NIOSH-190

Attachments: APhA Comments to NIOSH on Hazardous Drug List Proposed Revisions.doc

Please find attached APhA's comments to NIOSH on Hazardous Drug List Proposed Revisions. Thank you.

Jason Hansen, MS, JD
Health Policy Analyst, Government Affairs
American Pharmacists Association
2215 Constitution Avenue NW
Washington D.C. 20037-2985
800/237-APhA (2742)
202/448-8729
jhansen@aphanet.org
www.pharmacist.com

APhA was founded in 1852 as the American Pharmaceutical Association.

October is American Pharmacists Month!

October 3, 2011

National Institute for Occupational Safety and Health (NIOSH) Docket Office Robert A. Taft Lab MS-C34 4676 Columbia Parkway Cincinnati, Ohio 45226

[Submitted via e-mail at: nioshdocket@cdc.gov]

RE: Docket Number NIOSH-190. NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2012: Proposed Additions and Deletions to the NIOSH Hazardous Drug List.

Dear Sir/Madam:

The American Pharmacists Association (APhA) appreciates the opportunity to comment on the National Institute of Occupational Safety and Health (NIOSH) proposed additions and deletions to the "NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2012," that was published in the Federal Register on August 2, 2011 (76 FR 46299).

APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 62,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services. Specifically, the APhA Academy of Pharmacy Practice and Management (APhA-APPM) Section on Nuclear Pharmacy Practice is comprised of nearly 300 pharmacists involved in nuclear pharmacy practice and represents the broad scope of practice settings within this specialty.

APhA appreciates that in the notice NIOSH recognizes the existing regulatory authority over radiopharmaceuticals by the Nuclear Regulatory Commission (NRC) and supports the proposal to remove radiopharmaceuticals from the list, specifically ibritumomab tiuxetan and tositumomab. As we have advocated in the past, we agree that radiopharmaceuticals are sufficiently regulated by NRC through the controls in place to handle radiopharmaceuticals to address the primary hazard to the worker from ionizing radiation. We encourage NIOSH to exclude any radiopharmaceutical from the list unless their specific material safety data sheet indicates a primary hazard to the worker other than ionizing radiation, such as adverse reproductive outcomes, leukemic or other carcinogenic effects.

APhA Comments to Proposed NIOSH List of Hazardous Drugs in Health Care Settings 2012 October 3, 2011

Overall, we support NIOSH's efforts to revise the hazardous drug list to meet safety needs of health care providers. However, we encourage NIOSH to reconsider including commonly used and dispensed drugs that are not recommended for inclusion by the Advisory Panel, for example, tetracycline, statins, benzodiazepines, and serotonin-specific reuptake inhibitors (SSRIs). We are concerned that undue burden may be placed on health care providers because some drugs may not meet the threshold for exposure risk due to route of administration (e.g. drugs that are not absorbed through the skin), characteristics of the dosing form (e.g. the drug is contained in a capsule, coated tablet or vial), or exposure may be better mitigated by best practices for handling (e.g. drugs already handled in a room with specialized equipment designed for preparation of intravenous products).

Again, we appreciate and support NIOSH's efforts work on this important issue and ensure safety of health care providers. If you have any questions or require additional information, please contact Marcie Bough, Senior Director of Government Affairs, at mbough@aphanet.org, or at (202) 249-7538.

Sincerely,

Thomas E. Menighan, BSPharm, MBA, ScD (Hon), FAPhA

Executive Vice President and CEO

Thomas E. Mknighan

TM/mb

cc: Brian Gallagher, RPh, JD, Senior Vice President, Government Affairs

Anne Burns, RPh, Senior Vice President, Professional Affairs Marcie A. Bough, PharmD, Senior Director, Government Affairs