

29 June 2009

Docket Office
Robert A. Taft Laboratories
National Institute for Occupational
Safety and Health
4676 Columbia Parkway
MS C-34
Docket 105
Cincinnati, OH 45226

Re: NIOSH Hazardous Drugs List Update; Federal Register 74 FR 19570; 29 April 2009

To Whom it May Concern:

Thank you for the opportunity to submit comments on the NIOSH notice of draft document available for public comment on "Updating the List of Hazardous Drugs for the NIOSH Alert: Additions and Deletions to the NIOSH Hazardous Drug List," published on 29 April 2009 (74 FR 19570). The additions and deletions are intended to be added to the "NIOSH Alert: Preventing Occupational Exposures to Antineoplastic and other Hazardous Drugs in Healthcare Settings," DHHS Publication No. 2004-165 (2004), a document in which we have great interest (hereinafter "NIOSH Alert").

The BioPharma EHS Forum is an informal group comprised of biotechnology and biopharmaceutical companies that has met since 2004 to provide an opportunity for environmental, health and safety professionals within BioPharma companies to exchange ideas, share best practices, network, and benchmark with other companies. The goal of the BioPharma EHS Forum is to improve worker and environmental protection. Some of the BioPharma EHS Forum companies are submitting comments on their own behalf.

Obviously, the safe handling of hazardous drugs is an important issue for healthcare workers and for BioPharma EHS Forum member companies. We support NIOSH's efforts to revise the Alert to keep it current, and the inclusion of representative stakeholders, including manufacturers of biotherapeutic agents, in its Review Committee for the past several years. The BioPharma EHS Forum filed comments in 2007 in response to NIOSH's notice on 18 June 2007, 72 FR 33507. We appreciate your consideration of our comments.

Introduction

We believe that since NIOSH is a highly respected Agency, known for its scientific rigor, it is essential that the information NIOSH publishes be as accurate as possible. Healthcare workers

and employers rely on information provided by NIOSH for incorporation into training programs and to assure that proper precautions are taken in the workplace. These people will be especially interested in the revised Alert to understand the nature of the hazards and appropriate protective measures. Although we support NIOSH's findings regarding drugs to be added or deleted from the List, we have several comments below for NIOSH's consideration.

Comments

1. **Likelihood of Exposure and Mechanism of Action Considerations** – We strongly support NIOSH in its decision to “take into consideration the potential for exposure, among other factors.” We believe that the recognition that dose-response and bioavailability are appropriate considerations in determining whether a drug presents a true risk to the handler in a healthcare setting. NIOSH's decision has the net effect of significantly improving the effectiveness of the list in providing quality information for employers and employee regarding handling practices, and identifies those drugs that present real worker risk exposure. This assures that appropriate control measures can be implemented and training provided.
2. **NIOSH Consistency** – We appreciate the effort undertaken by NIOSH to assure that the information in the Alert is consistent with other recommendation to avoid confusion for both employers and employees. We support this approach.
3. **Scientific Methodology for Conclusion to Add or Delete Drugs** – We appreciate that NIOSH described its approach in its Response to Public Comments (available by clicking that icon from [here](#)). On page one, NIOSH set forth its process of assessing each drug individually, rather than classes of drugs, and it evaluated evidence found in the Prescribing Information for organ toxicity, reproductive toxicity, genotoxicity, carcinogenicity, teratogenicity, and potency (information was from the drug package inserts).

Recommendation: NIOSH formalize its methodology by incorporating its process into the “NIOSH Alert” rather than having it appear separately on the website under “Response to Public Comments.” This would be important for healthcare workers as well as to other stakeholders in better understanding and implementing the Alert as well as in making their internal determinations going forward.

4. **Definition of “hazardous drug”** – NIOSH states on page two of its Response to Public Comments that the NIOSH Working Group revised the definition of hazardous drugs. This is important information for the healthcare workers and management in better understanding the NIOSH Alert and making decisions regarding appropriate controls.

Recommendation: NIOSH include the new definition of “hazardous drugs” in the revised Alert for healthcare worker and employer clarity.

5. **Conclusion to Add or Delete Drugs** – We believe that it is important to have a brief summary of how the assessment process described in (1) above was applied to each of the drugs evaluated, whether by a table or in narrative form to make it clear how the conclusion

was reached. Healthcare workers and employers will thereby be able to understand the basis for the adding or deleting of a drug.

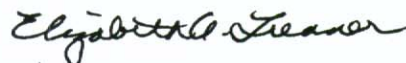
Recommendation: NIOSH add to the Alert a summary or overview of the specific basis for each conclusion that a drug should be added or deleted from the list.

Conclusion

We support NIOSH in its decision to consider mechanism of action and exposure because it will provide scientifically accurate information that can be implemented to protect workers. Employers and employees will make workplace control and training decisions based on the Alert. We believe it would be inappropriate for employers and workers to develop training programs and take measures that do not reflect the hazards that exist.

Thank you for your consideration of these comments. We would be pleased to discuss them further with you or members of the NIOSH staff.

Sincerely,



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Chair
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