

before the committee. Written submissions may be made to the contact person on or before August 15, 2011. Oral comments from the public will be scheduled between approximately 2 and 3 p.m./Eastern Time. Time allotted for each presentation will be limited to three minutes each. If the number of speakers requesting to comment is greater than can be reasonably accommodated during the scheduled open public hearing session, ONC will take written comments after the meeting until close of business.

Persons attending ONC's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

ONC welcomes the attendance of the public at its advisory committee meetings. Seating is limited at the location, and ONC will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Judy Sparrow at least seven (7) days in advance of the meeting.

ONC is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://healthit.hhs.gov> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (Pub. L. 92-463, 5 U.S.C., App. 2).

Dated: July 25, 2011.

Judith Sparrow,
Office of Programs and Coordination, Office of the National Coordinator for Health Information Technology.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[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

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of Draft Document Available for Public Comment.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the availability of the following draft document for public comment entitled "NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2012: Proposed Additions and Deletions to the NIOSH Hazardous Drug List." The document and instructions for submitting comments can be found at <http://www.cdc.gov/niosh/docket/review/docket190/default.html>.

This guidance document does not have the force and effect of law.

Public Comment Period: Comments must be received by October 3, 2011.

ADDRESSES: Written comments may be submitted to the NIOSH Docket Office, identified by Docket Number NIOSH-190, by any of the following methods:

- **Mail:** NIOSH Docket Office, Robert A. Taft Laboratories, MS-C34, 4676 Columbia Parkway, Cincinnati, Ohio 45226.
- **Facsimile:** (513) 533-8285.
- **E-mail:** nioshdocket@cdc.gov.

All information received in response to this notice will be available for public examination and copying at the NIOSH Docket Office, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

A complete electronic docket containing all comments submitted will be available on the NIOSH web page at <http://www.cdc.gov/niosh/docket>, and comments will be available in writing by request. NIOSH includes all comments received without change in the docket, including any personal information provided. All electronic comments should be formatted as Microsoft Word. Please make reference to Docket Number NIOSH-190.

SUPPLEMENTARY INFORMATION:

Background: The NIOSH Alert: Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings was published in September 2004 (<http://www.cdc.gov/niosh/docs/2004-165/>). This Alert contained Appendix A which was a list of drugs that were deemed to be hazardous and may require special handling. This list of hazardous drugs was updated in 2010 and covered all new approved drugs and drugs with new warning since 2007 (<http://www.cdc.gov/niosh/docs/2010-167/>). Between June 2007 and December 2009, 48 new drugs received FDA approval and 115 drugs received special warnings (usually black box warnings) based on reported adverse effects in patients. The complete list of these drugs can be found at: <http://www.cdc.gov/niosh/>

[docket/review/docket190/pdfs/Proposedchanges07112011.pdf](http://www.cdc.gov/niosh/docket/review/docket190/pdfs/Proposedchanges07112011.pdf). From this list of 169 drugs, 45 drugs were identified by NIOSH as candidate hazardous drugs. Seven of these drugs had safe handling recommendations from the manufacturer and NIOSH is accepting these recommendations as appropriate. Therefore, these seven drugs will be listed as hazardous without requiring further review. A panel consisting of peer reviewers and stakeholders was asked to review and comment on the remaining 38 potentially hazardous drugs. In addition, the panel members were asked to comment on the removal of 15 drugs from the 2010 Hazardous Drug List. Reviewers were not asked to provide a consensus opinion and NIOSH made the final determination regarding additions and deletions to the 2010 hazardous drug List.

NIOSH reviewed the recommendations of the peer reviewers and stakeholders and determined that 24 drugs in addition to the 7 drugs with manufacturer's warnings, were determined to have one or more characteristics of a hazardous drug and this list of 31 drugs is being published for comment in NIOSH Docket Number 190. In addition, 15 drugs from the 2010 Hazardous Drug List are being considered for removal. Four drugs were evaluated for reclassification, two drugs are radio-pharmaceuticals which are covered by specific handling regulations set by the Nuclear Regulatory Commission and nine others are not available in the United States at this time. In order to keep the list as current as possible, NIOSH will remove any drugs that are no longer available in the United States. If any of these drugs were to become available at a later date, NIOSH would reconsider them for review.

FOR FURTHER INFORMATION CONTACT: Barbara MacKenzie, NIOSH, Robert A. Taft Laboratories, 4676 Columbia Parkway, MS-C26, Cincinnati, Ohio 45226, telephone (513) 533-8132, E-mail hazardousdrugs@cdc.gov.

Reference: <http://www.cdc.gov/niosh/docket/review/docket190/pdfs/PanelSummary05092011.pdf>.

Dated: July 22, 2011.

John Howard,
Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

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