

decompressed with data from the Edel-Kindwall Tables,(3) Information on related control measures (e.g., engineering controls, work practices, personal protective equipment) in use in workplaces where decompression is required, and (4) Information on alternative tables and approaches being used to protect tunneling workers from higher pressures greater than 50 psi.

References

1. Hamilton RW, Bill Kay E. (2008) *Boring deep tunnels. Third conference on U.S.-Japan panel on aerospace-diving physiology & technology and hyperbaric medicine.*
2. Downs GJ, Kindwall EP. (1986) Aseptic necrosis in caisson workers: A new set of decompression tables. *Aviat Space & Environ Med* 57:569–574.

Dated: December 4, 2012.

John Howard,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number NIOSH–238]

Issuance of Final Guidance Publication

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 issuance of final guidance publication.

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 publication: NIOSH Alert entitled “Preventing Occupational Respiratory Disease from Exposures Caused by Dampness in Office Buildings, Schools, and Other Nonindustrial Buildings” [2013–102].

ADDRESSES: This document may be obtained at the following link:

- *Web site:* <http://www.cdc.gov/niosh/docs/2013-102/>.

FOR FURTHER INFORMATION CONTACT: Michelle R. Martin, M.S., NIOSH/CDC, 1095 Willowdale Road, Morgantown, WV 26505, telephone (304) 285–5734, email mrmartin1@cdc.gov.

Dated: December 4, 2012.

John Howard,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0429]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance on Meetings With Industry and Investigators on the Research and Development of Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by January 14, 2013.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910–NEW and title “Guidance on Meetings With Industry and Investigators on the Research and Development of Tobacco Products.” Also, include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, Daniel.Gittleson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance on Meetings With Industry and Investigators on the Research and Development of Tobacco Products—(OMB Control Number 0910–NEW)

This guidance is intended to assist tobacco manufacturers, importers, researchers, and investigators, and their representatives who seek meetings with staff of FDA’s Center for Tobacco Products (CTP) relating to their plans to conduct research to inform the regulation of tobacco products or support the development or marketing of tobacco products. This guidance does not pertain to other types of meetings or meeting requests with CTP staff. The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) offers tobacco product manufacturers several pathways to obtain an order from FDA to authorize the marketing of a tobacco product before it may be introduced or delivered into interstate commerce. To provide assistance with these pathways to market particular products, FDA will meet with tobacco product manufacturers, importers, researchers, and investigators (or their representatives) where appropriate. This guidance is intended to assist persons who seek guidance relating to their research to inform the regulation of tobacco products, or to support the development or marketing of tobacco products. In the guidance, the Agency discusses, among other things:

- What information DA recommends persons include in such a meeting request;
- How and when to submit such a request; and
- What information FDA recommends persons submit prior to such a meeting.

In the **Federal Register** of May 25, 2012 (77 FR 31368), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one response containing PRA-related comments.. The comment indicated that the guidance should clarify that meeting request times will vary depending on the type of submission to be discussed and the meeting information package requirements should be tailored to the submission type.

In response, the estimated burden hours for both meeting requests and meeting information package requirements have been calculated by FDA and are based on an average number of hours for each type of submission over a 3-year period. The meeting information requirements are also averaged together and are not individually split into submission types