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.

[FR Doc. 2012–30080 Filed 12–12–12; 8:45 am]

BILLING CODE 4163–19–P

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.

[FR Doc. 2012–30081 Filed 12–12–12; 8:45 am]

BILLING CODE 4163–19–P

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 *oira_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

for this collection. The commenter also provided comments that were not PRA-related and are beyond the scope of this document.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Meeting requests and information packages	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Meeting Requests					
Combining and sending meeting request letters for manufacturers, importers, and researchers	67	1	67	10	670
Meeting Information Packages					
Combining and submitting meeting information packages for manufacturers, importers, and researchers.	67	1	67	18	1,206
Collection Totals					1,876

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA's estimate of the number of respondents for meeting requests in table 1 of this document is based on the number of meeting requests to be received over the next three years. In year 1 of this collection, FDA estimates that 50 preapplication meetings will be requested. In year 2, FDA estimates that 100 meetings will be requested, especially as applications and reports for substantial equivalence, etc., are received and acted upon. Once the public knows more about submitting these applications in year 3 three, the request for meetings is expected to drop back to the year 1 one rate of 50 per year. Thus, FDA estimates the number of manufacturers, importers, researchers, and investigators who are expected to submit meeting requests in table 1 of this document to be 67 (50 year 1 requests + 100 year 2 requests + 50 year 3 requests divided by 3). The hours per response, which is the estimated number of hours that a respondent would spend preparing the information recommended by the guidance to be submitted with a meeting request, is estimated to be approximately 10 hours each, and the total burden hours are 670 hours (10 hours preparation/mailing times 67 average respondents per year). Based on FDA's experience, the Agency expects it will take respondents this amount of time to prepare, gather, copy, and submit brief statements about the product and a description of the purpose and details of the meeting.

FDA's estimate of the number of respondents for compiling meeting information packages in table 1 of this document is based on 67 respondents each preparing copies of their information package and submitting them to FDA, for a total of 1,206 hours annually. The hours per response, which is the estimated number of hours that a respondent would spend preparing the information package as recommended by the guidance, is estimated to be approximately 18 hours per information package. Based on FDA's experience, the Agency expects that it will take respondents 1,206 hours of time (67 respondents times 18 hours) to gather, copy, and submit brief statements about the product, a description of the details of the anticipated meeting, and data and information that generally would already have been generated for the planned research and/or product development. The total number of burden hours for this collection of information is 1,876 hours (670 hours to prepare and submit meeting requests and 1,206 hours to prepare and submit information packages).

Dated: December 7, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–30057 Filed 12–12–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–1161]

Draft Guidance for Industry and Food and Drug Administration Staff; Design Considerations for Devices Intended for Home Use; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Design Considerations for Devices Intended for Home Use.'' This document is intended to assist manufacturers in designing and developing home use medical devices that comply with applicable standards of safety and effectiveness and other regulatory requirements. Home use devices are associated with unique risks created by the interactions among the user (often a layperson), the use environment, and the device. This document identifies several factors that manufacturers should consider, especially during device design and development, and provides recommendations for reducing or minimizing these unique risks. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by March 13, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Design Considerations for Devices Intended for Home Use'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development (HFM–40), Center for