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

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

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 FDA recommends persons include in such a meeting 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 of 60 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.
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, 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 an estimated 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 prepared 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).


Leslie Kux, Assistant Commissioner for Policy.

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 Communications, Outreach and Development.

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.

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