ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Track 1 Nominations: Effective Programs	10–30	1	6	60–180
Track II Nominations: Innovative Programs	150–200	1	4	600–800
Estimated Total Annual Burden Hours				660–980

Additional Information: Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, Attn: Desk Officer for ACF.

Dated: February 6, 2002.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 02–3353 Filed 2–11–02; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01B–0431]

International Conference on Harmonisation; Draft Recommendations for the Revision of the Permitted Daily Exposures for Two Solvents, N-Methylpyrrolidone and Tetrahydrofuran, According to the Maintenance Procedures for the Guidance Q3C Impurities: Residual Solvents; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of draft recommendations for the revision of the permitted daily exposures (PDE) for two solvents, n-methylpyrrolidone (NMP) and tetrahydrofuran (THF), according to the maintenance procedures for guidance for industry entitled ''Q3C Impurities: Residual Solvents.'' The draft recommendations were prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). This document also describes procedures for proposing future revisions to the PDE.

DATES: Submit written or electronic comments on the draft recommendations by March 14, 2002.

ADDRESSES: Submit written comments on the draft recommendations to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Submit written requests for single copies of these draft recommendations to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852–1448, FAX 888–CBERFAX. Send two self-addressed adhesive labels to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to documents and maintenance procedures.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Robert Osterberg, Center for Drug Evaluation and Research (HFD–520), Food and Drug Administration, 5600 Fishers Lane,Rockville, MD 20857, 301–827–2120.

Regarding the ICH: Janet J. Showalter, Office of International Programs (HFG–1),Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0865.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, the Canadian Health Protection Branch, and the European Free Trade Area.

In accordance with FDA's good guidance practices (GGPs) regulation (65 FR 56468, September 19, 2000), this document is being called a guidance, rather than a guideline.

To facilitate the process of making ICH guidances available to the public, the agency has changed its procedure for publishing ICH guidances. As of April 2000, we no longer include the text of ICH guidances in the **Federal Register**. Instead, we publish a notice in the **Federal Register** announcing the availability of an ICH guidance. The ICH guidance will be placed in the docket and can be obtained through regular agency sources (see the **ADDRESSES** section). Draft guidances are left in the original ICH format. The final guidance is reformatted to conform to the GGP style before publication.

In the **Federal Register** of December 24, 1997 (62 FR 67377), FDA published the ICH guidance for industry entitled ''Q3C Impurities: Residual Solvents.'' The guidance makes recommendations as to what amounts of residual solvents are considered safe in pharmaceuticals. The guidance recommends use of less toxic solvents and describes levels considered to be toxicologically acceptable for some residual solvents. Upon issuance in 1997, the text and appendix 1 of the guidance contained several tables and a list of solvents categorizing residual solvents by toxicity, classes 1 through 3, with class 1 being the most toxic. The Quality Expert Working Group (EWG) agreed that the PDE could be modified if reliable and relevant toxicity data were brought to the attention of the group and that the modified PDE would result in a revision of the tables and list.

In 1999, ICH instituted a Q3C maintenance agreement and formed a maintenance EWG (Q3C EWG). The agreement provided for the revisitation of solvent PDEs and allowed for minor changes to the tables and list that include the existing PDEs. The agreement also provided that new solvents and PDEs could be added to the tables and list based on adequate toxicity data. This notice announces the availability of draft recommendations for the revision of the PDE for NMP and THF according to the Q3C maintenance procedures. It also briefly describes the process for proposing future revisions to the PDE.

II. Draft Recommendations to Revise the Tables and List

In July of 2000, the ICH Steering Committee agreed that draft proposals and recommendations to revise the PDE for the solvents NMP and THF should be made available for public comment. The draft recommendations are the product of the Q3C EWG review of new data.

A. N-Methylpyrrolidone (NMP)

The Q3C EWG received new toxicity data for the solvent NMP in late 1999. The data had been provided to FDA by the NMP producers group, who had proposed moving NMP from class 2 to class 3. The data resulted from a 2-year chronic feeding study in rats performed by E.I. Dupont de Nemours & Co (unpublished data). The data were sent to the members of the Q3C EWG for their analysis. These data appeared to be the best available upon which to make a recommendation to the ICH Steering Committee regarding a change in the status of NMP. At the last ICH meeting, February 28 to March 2, 2000, the ICH Steering Committee was briefed on the results of the EWG's analysis. The recommendation was to keep NMP in class 2 and to reduce the PDE. The analysis and the draft recommendation are available for review at http://www.fda.gov/cder/audiences/iact/iachome.htm. They are also available from the Division of Drug Information (HFD–240); address above.

B. Tetrahydrofuran (THF)

The Q3C EWG reviewed new toxicity data for the solvent THF. The data were published by the U.S. National Toxicology Program and consisted of data from several mutagenicity studies and two carcinogenicity studies in rodents via the inhalational route of administration. Information was sent to the members of the Q3C EWG for their analysis. At the last ICH meeting, February 28 to March 2, 2000, the ICH Steering Committee was briefed on the results of the Q3C EWG's analysis. The recommendation was to move THF from class 3 into class 2. The analysis and the draft recommendation are available for review at http://www.fda.gov/cder/audiences/iact/iachome.htm. They are also available from the Division of Drug Information (HFD–240) (address above).

The agency is interested in comments on the draft recommendations regarding the classification of NMP and THF. Comments about the draft recommendations will be considered by FDA and the Q3C EWG.

III. Process for Proposing Future Revisions

In November 2000, the ICH Steering Committee agreed to formalize the maintenance procedures for the guidance entitled ''Q3C Impurities: Residual Solvents.'' The maintenance procedures include multiple ways to establish a PDE for a new solvent or to revise a PDE for an already classified solvent. A proposal with supporting information can be submitted to the ICH Secretariat, to the regulatory agency via the public docket, or to an ICH-involved scientist in an agency or in a pharmaceutical company to submit to the ICH Secretariat. The maintenance procedures state that this information should be based on significant toxicity data from studies such as genotoxicity studies, repeat-dose studies, reproductive toxicity studies, and/or other relevant toxicology studies. Single-dose toxicity data alone are not sufficient. The toxicity data should be of good laboratory practice quality and sufficient to calculate a PDE for a new solvent that will place the new solvent into a toxicity class.

The details of the ICH Q3C maintenance procedures are available on the Internet at http://www.fda.gov/cder/audiences/iact/iachome.htm.

IV. Procedural Changes to Facilitate the Maintenance Process

To facilitate the maintenance process, FDA has decided to delink the tables and list from the Q3C guidance and create a stand alone guidance entitled ''Q3C: Tables and List.'' Creating a stand alone document will enable the agency to update the tables and list when ICH endorses a recommendation to recategorize, remove, or add solvents without revising the Q3C guidance. In addition, the 1997 guidance has been reformatted consistent with FDA's good guidance practices regulation (21 CFR 10.115). Both the reformatted Q3C guidance and the delinked tables and list are available on the agency's Web sites.

The availability of draft and final recommendations for revisions of PDEs and classifications will be announced through a notice in the **Federal Register**. In addition, an FDA Web site at http://www.fda.gov/cder/audiences/iact/iachome.htm details the maintenance procedures, provides contact information, and allows the dissemination of the revised information as quickly as possible. In the future, notices in the **Federal Register** announcing proposals and draft and final recommendations to change the list will send the reader to the Web site for details.

The Q3C EWG's draft recommendations for the two solvents will, when finalized, represent the agency's current thinking on this topic. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on the recommendations to change the list by March 14, 2002. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft recommendations and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Persons with access to the Internet may obtain the Q3C documents at http://www.fda.gov/cder/guidance/index.htm, or http://www.fda.gov/cber/guidelines.htm. Information on the Q3C maintenance process as well as proposals, data analysis, and draft and final recommendations for revisions to the tables and list are being made available at http://www.fda.gov/cder/audiences/iact/iachome.htm. The electronic address for submitting comments to Dockets Management Branch is http://www.fda.gov/dockets/ecomments.

Dated: February 5, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–3388 Filed 2–11–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Peripheral and Central Nervous System Drugs Advisory Committee Meeting; Cancellation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is cancelling the meeting of the Peripheral and Central Nervous System Drugs Advisory Committee scheduled for February 15, 2002. The meeting was announced in the **Federal Register** of January 22, 2002 (67 FR 2891 to 2892).

FOR FURTHER INFORMATION CONTACT: Sandra Titus, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301 827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12543.

Dated: February 6, 2002.

Bonnie H. Malkin,

Acting Senior Associate Commissioner for Communications and Constituent Relations.

[FR Doc. 02–3372 Filed 2–11–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0577]

Medical Devices; Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide ($PcCO_2$) and Oxygen (PcO_2) Monitors; Draft Guidance for Industry and FDA; 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 ''Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide ($PcCO_2$) and Oxygen (PcO_2) Monitors; Draft Guidance for Industry and FDA.'' This draft guidance will serve as a special control for cutaneous carbon dioxide ($PcCO_2$) and cutaneous oxygen (PcO_2) monitor devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to reclassify these device types. This draft guidance is neither final nor is it in effect at this time.

DATES: Submit written or electronic comments on this guidance by May 13, 2002.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide ($PcCO_2$) and Oxygen (PcO_2) Monitors; Draft Guidance for Industry and FDA'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: William A. Noe, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8609, ext. 174.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance document describes a means by which cutaneous carbon dioxide ($PcCO_2$) and cutaneous oxygen (PcO_2) monitor devices may comply with the requirement of special controls for class II devices. Designation of this guidance document as a special control means that manufacturers attempting to establish that their device is substantially equivalent to a predicate carbon dioxide ($PcCO_2$) or oxygen (PcO_2) monitor device must demonstrate that the proposed device complies with either the specific recommendations of this guidance or some alternate control that provides equivalent assurances of safety and effectiveness.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on ''Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide ($PcCO_2$) and Oxygen (PcO2) Monitors; Draft Guidance for Industry and FDA.'' It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

In order to receive ''Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide ($PcCO_2$) and Oxygen (PcO_2) Monitors; Draft Guidance for Industry and FDA'' via your fax machine, call the CDRH Facts-On-Demand system at 800 –899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1335) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access.