

Representatives, the Head Start Bureau has prepared a survey form to be mailed to and completed by all Head Start

grantees and delegate agencies within 30 days. The Head Start Bureau will then compile the results and forward

the requested information to the Committee.

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Completion of HSB Survey (new web-based form)	2700	1x only5	1,350
Retrieval and submission of existing IRS Form 990, SF424, and PIR data	2700	1x only	8.5	22,950

Estimated Total Burden Hours: 24,300 hours.

Additional Information: The Administration for Children and Families is requesting that OMB grant a 30-day approval for this information collection under procedures for emergency processing by December 8, 2003. A copy of this information collection, with applicable supporting documentation, may be obtained by calling the Administration for Children and Families, Reports Clearance Officer, Robert Sargis at (202) 690-7275. In addition, a request may be made by sending an e-mail request to: rsargis@acf.hhs.gov.

Comments and suggestions about the information collection described above should be directed to the following e-mail address at the Office of Information and Regulatory Affairs, Office of Management and Budget, Paper Reduction Project: Lauren_Wittenberg@omb.eop.gov.

Dated: November 6, 2003.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2001B-0431]

International Conference on Harmonisation; Final Recommendations on 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 final recommendations to revise the permitted daily exposures (PDEs) for

two solvents, n-methylpyrrolidone (NMP) and tetrahydrofuran (THF), according to the maintenance procedures for the guidance for industry entitled "Q3C Impurities: Residual Solvents." The final recommendations were reached under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

DATES: Submit written or electronic comments on guidance documents at any time.

ADDRESSES: Submit written comments on the analyses and recommendations to revise the PDEs for NMP and THF to the Division of Dockets Management (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 the documents 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 888-223-7329. 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 Q3C guidance: Robert Osterberg, Center for Drug Evaluation and Research (HFD-520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2120; or Andrew Shrake, Center for Biologics Evaluation and Research (HFM-345), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1148, 301-402-4635.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG-1), Food and Drug

Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0864.

SUPPLEMENTARY INFORMATION:

I. Background

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