

and programmed electronic report entry, which transitioned to the National Tuberculosis Indicators Project (NTIP), a secure web-based system for program evaluation data, in 2010. No other federal agency collects this type of national tuberculosis data, and the Aggregate report of follow-up for

contacts of tuberculosis, and Aggregate report of screening and preventive therapy for tuberculosis infection are the only data source about latent tuberculosis infection for monitoring national progress toward tuberculosis elimination with these activities. CDC provides ongoing assistance in the

preparation and utilization of these reports at the local and state levels of public health jurisdiction. CDC also provides respondents with technical support for the NTIP software (Electronic—100%, Use of Electronic Signatures—No).

There is no cost to respondents.

#### ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Data clerks and Program Managers.	Follow-up and Treatment of Contacts to Tuberculosis Cases Form.	100	1 (electronic) .....	30/60	50
Program Managers .....	Follow-up and Treatment of Contacts to Tuberculosis Cases Form.	18	1 (manual) .....	30/60	9
Data clerks .....	Follow-up and Treatment of Contacts to Tuberculosis Cases Form.	18	1 (manual) .....	3	54
Data clerks and Program Managers.	Targeted Testing and Treatment for Latent Tuberculosis Infection.	100	1 (electronic) .....	30/60	50
Program Managers .....	Targeted Testing and Treatment for Latent Tuberculosis Infection.	18	1 (manual) .....	30/60	9
Data clerks .....	Targeted Testing and Treatment for Latent Tuberculosis Infection.	18	1 (manual) .....	3	54
Total .....	.....	.....	.....	.....	226

#### Ron A. Otten,

Director, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Centers for Disease Control and Prevention

#### Disease, Disability, and Injury Prevention and Control Special Emphasis Panels (SEP): Initial Review

The meeting announced below concerns Conducting Public Health Research in Kenya, FOA GH10-003; Conducting Public Health Research in Thailand by the Ministry of Public Health (MOPH), FOA GH11-002; Conducting Public Health Research in China, FOA GH12-005; Strengthening Disease Prevention Research Capacity for Public Health Action in Guatemala and the Central American Region, FOA GH13-001; Detecting Etiologies of Emerging Infectious Diseases at the Regional Level—Western Ghat Region of Karnataka and Kerala, India, FOA

GH13-003; Strengthening Surveillance for Japanese Encephalitis in India, FOA GH13-004; and Research and Technical Assistance for Public Health Interventions in Haiti to Support Post-earthquake Reconstruction, Cholera and HIV/AIDS, FOA GH13-006, initial review.

*Correction:* The notice was published in the **Federal Register** on April 4, 2013, Volume 78, Number 65, Pages 20319–20320. The meeting announced and matters to be discussed should read as follows:

Conducting Public Health Research in Kenya, FOA GH10-003; Conducting Public Health Research in Thailand by the Ministry of Public Health (MOPH), FOA GH11-002; Conducting Public Health Research in China, FOA GH12-005; Strengthening Disease Prevention Research Capacity for Public Health Action in Guatemala and the Central American Region, FOA GH13-001; Detecting Etiologies of Emerging Infectious Diseases at the Regional Level—Western Ghat Region of Karnataka and Kerala, India, FOA GH13-003; Strengthening Surveillance for Japanese Encephalitis in India, FOA GH13-004; and Research and Technical Assistance for Public Health Interventions in Haiti to Support Post-

earthquake Reconstruction, Cholera and HIV/AIDS, FOA GH13-006.

*Matters To Be Discussed:* The meeting will include the initial review, discussion, and evaluation of applications received in response to “Conducting Public Health Research in Kenya, FOA GH10-003; Conducting Public Health Research in Thailand by the Ministry of Public Health (MOPH), FOA GH11-002; Conducting Public Health Research in China, FOA GH12-005; Strengthening Disease Prevention Research Capacity for Public Health Action in Guatemala and the Central American Region, FOA GH13-001; Detecting Etiologies of Emerging Infectious Diseases at the Regional Level—Western Ghat Region of Karnataka and Kerala, India, FOA GH13-003; Strengthening Surveillance for Japanese Encephalitis in India, FOA GH13-004; and Research and Technical Assistance for Public Health Interventions in Haiti to Support Post-earthquake Reconstruction, Cholera and HIV/AIDS, FOA GH13-006, initial review.”

*Contact Person for More Information:* Lata Kumar, Scientific Review Officer, CGH Science Office, Center for Global Health, CDC, 1600 Clifton Road, NE.,

Mailstop D-69, Atlanta, Georgia 30033, Telephone (404) 639-7618.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-D-0369]

#### International Conference on Harmonisation; Draft Guidance on M7 Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals To Limit Potential Carcinogenic Risk; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled “M7 Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk.” The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance emphasizes considerations of both safety and quality risk management in establishing levels of mutagenic impurities that are expected to pose negligible carcinogenic risk. It outlines recommendations for assessment and control of mutagenic impurities that reside or are reasonably expected to reside in a final drug substance or product, taking into consideration the intended conditions of human use. The draft guidance is intended to provide guidance for new drug substances and new drug products during their clinical development and subsequent applications for marketing.

**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 June 14, 2013.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993-0002, or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

#### FOR FURTHER INFORMATION CONTACT:

*Regarding the guidance:*

David Jacobson-Kram, Office of New Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5299, Silver Spring, MD 20993-0002, 301-796-0175.

*Regarding the ICH:*

Michelle Limoli, International Programs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3342, Silver Spring, MD 20993-0002, 301-796-8377.

#### 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, Health Canada, and the European Free Trade Area.

In February 2013, the ICH Steering Committee agreed that a draft guidance entitled “M7 Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk” should be made available for public comment. The draft guidance is the product of the M7 Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the M7 Expert Working Group.

The draft guidance provides guidance on the regulation of genotoxic impurities in new drug substances and drug products.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on this topic. 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 statutes and regulations.

##### II. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It