

Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448, 301-827-6210.

Regarding the ICH: Michelle Limoli, Center for Drug Evaluation and Research, International Programs, 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; CDER and CBER, 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In the **Federal Register** of July 14, 2010 (75 FR 40843), FDA published a notice announcing the availability of a draft guidance entitled "Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions; Annex 13: Bulk

Density and Tapped Density of Powders General Chapter." The notice gave interested persons an opportunity to submit comments by September 13, 2010.

After consideration of the comments received and revisions to the guidance, a final draft of the guidance was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies in June 2012.

The guidance provides the specific evaluation results from the ICH Q4B process for the Bulk Density and Tapped Density of Powders General Chapter harmonized text originating from the three-party PDG. This guidance is in the form of an annex to the core ICH Q4B guidance (<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073405.pdf>) made available in the **Federal Register** of February 21, 2008 (73 FR 9575). The annex will provide guidance to assist industry and regulators in the implementation of the specific topic evaluated by the ICH Q4B process.

This 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 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 is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.regulations.gov>, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

Dated: May 21, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0510]

Clinical Development Programs for Opioid Conversion; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA), Center for Drug Evaluation and Research, is announcing a public scientific workshop to address public health concerns associated with the inclusion of equianalgesic opioid conversion tables in opioid product labels. Discussion will focus on the available data supporting the use of equianalgesic opioid conversion tables, problems associated with their use, and strategies used in clinical practice to convert patients from one opioid analgesic product to another. The goal of the workshop is to identify gaps in existing knowledge regarding equianalgesic opioid conversion in clinical practice, to develop a research agenda to address these gaps, and to identify mechanisms for communicating safe opioid analgesic conversion strategies to prescribers.

Date and Time: The public workshop will be held on July 29, 2013, from 8 a.m. to 4:30 p.m.

Location: The workshop will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Entrance for non-FDA employees is through Building 1 where routine security check procedures will be performed. For parking and security information, please visit <http://www.fda.gov/AboutFDA/WorkingatFDA/Buildingsandfacilities/WhiteOakCampusInformation/ucm241740.htm>.

Contact Persons: Elizabeth Giaquinto, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-3416, Elizabeth.Giaquinto@fda.hhs.gov, or Lisa Basham, Center for Drug Evaluation

and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-1175,
Lisa.Basham@fda.hhs.gov.

Registration to Attend the Workshop and Requests to Participate in Open Public Hearing: As part of the public workshop, an open public hearing will be held between 10:15 a.m. and 11:15 a.m. on July 29, 2013. If you wish to attend the public workshop or provide testimony for the open public hearing, please email your registration to: IssuesWithOpioids@fda.hhs.gov by July 15, 2013. Those without email access may register by contacting one of the persons listed in the *Contact Persons* section of the document. Please provide complete contact information for each attendee, including name, title, affiliation, address, email address, and telephone number.

For those interested in providing testimony for the Open Public Hearing, please also provide a short abstract of your remarks by July 15, 2013. We will try to accommodate all persons who wish to testify; however, the duration of each speaker's testimony during this open public hearing may be limited by time constraints.

Registration for the public workshop is free and will be on a first-come, first-served basis. Early registration is recommended, because seating is limited. FDA may limit the number of participants from each organization as well as the total number of participants based on space limitations. Registrants will receive confirmation once they have been accepted for the workshop. Onsite registration on the day of the meeting will be based on space availability. If registration reaches maximum capacity, FDA will post a notice closing meeting registration for the workshop at: <http://www.fda.gov/Drugs/NewsEvents/ucm340470.htm>.

Comments: Submit either electronic or written comments by August 29, 2013. Submit electronic comments 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. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

If you need special accommodations due to a disability, please contact Elizabeth Giaquinto or Lisa Basham (see

Contact Persons) at least 7 days in advance of the public workshop.

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA is announcing this workshop to address public health concerns associated with the inclusion of equianalgesic opioid conversion tables in opioid product labels. Use of these conversion tables, intended for safe conversion between opioid products, has resulted in prescribing errors, serious adverse events, and deaths. While FDA will be giving a brief presentation on the use of conversion tables in the current product labels, we are holding this scientific workshop to bring the academic experts together to achieve consensus on what does or does not need to be done to improve how opioids are converted in clinical practice.

During the public workshop participants will do the following:

1. Review the data available supporting the basis of equianalgesic opioid conversion tables.
2. Review the problems associated with the use of equianalgesic opioid conversion tables, including prescribing errors and the occurrence of serious adverse events and deaths, with emphasis on the risks associated with extended-release opioids.
3. Review clinical strategies used for converting patients from one opioid product to another opioid product and the data to support the safety of those strategies.
4. Discuss gaps in the existing knowledge regarding equianalgesic opioid analgesic doses and opioid conversion in clinical practice.
5. Develop a research agenda to address those gaps.
6. Discuss the mechanisms for communicating about safe opioid analgesic conversion strategies to prescribers.

FDA will post the agenda and additional workshop background material approximately 5 days before the workshop at: <http://www.fda.gov/Drugs/NewsEvents/ucm340470.htm>.

II. Transcripts

Please be advised that approximately 30 days after the public workshop, a transcript will be available. It will be accessible at <http://www.regulations.gov>, and may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information

(ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: May 21, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received within 60 days of this notice.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 10-29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call the HRSA Information Collection Clearance Officer at (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Children's Hospital Graduate Medical Education Payment Program (CHGME PP) Annual Report OMB No. 0915-0313—Extension

Abstract: The CHGME Payment Program was enacted by Public Law 106-129 to provide Federal support for