II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/cdrh/pmapage.html*.

Dated: August 22, 2005.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 05–17602 Filed 9–2–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0324]

International Conference on Harmonisation; Draft Guidance on M5 Data Elements and Standards for Drug Dictionaries; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''M5 Data Elements and Standards for Drug Dictionaries.'' The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use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 The draft guidance describes the data elements and standards that ICH recommends be made available to interested parties to assist in the development and maintenance of drug dictionaries. The draft guidance is intended to facilitate the exchange and practical use of medicinal product information at the international level, such as with postmarketing safety reporting.

DATES: Submit written or electronic comments on the draft guidance by October 21, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857;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 (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. The draft guidance may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. Send two self-addressed adhesive labels to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Randy Levin, Center for Drug Evaluation and Research (HFD–001), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7784; or Ann Schwartz, Center for Biologics Evaluation and Research (HFM–475), Food and Drug Administration, 1401 Rockville Pike, rm. 300N, Rockville, MD 20832, 301–827–3070.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

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 ICH's sponsors and IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In May 2005, the ICH Steering Committee agreed that a draft guidance entitled ''M5 Data Elements and Standards for Drug Dictionaries'' should be made available for public comment. The draft guidance is the product of the M5 Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the M5 expert working group.

The draft guidance describes the data elements that ICH recommends be made available to interested parties to assist in the development and maintenance of drug dictionaries. The draft guidance outlines each data element and provides recommended standards for the data elements. The draft guidance addresses medicinal products (drugs and biologics) and is intended to accomplish the following goals:

- Improve the exchange of medicinal product information,
- Improve consistency in evaluating and comparing medicinal products for postmarketing surveillance activities,
- Provide consistent terminology for the health care community, and
- Reduce administrative burdens for the pharmaceutical industry when complying with different regional regulatory requirements.

The draft guidance refers to approved medicinal products. The draft guidance does not apply to homeopathic medicinal products or investigational medicinal products. The draft guidance does not cover the establishment and maintenance of a drug dictionary.

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 M5 data elements and standards for drug dictionaries. 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 to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/ohrms/dockets/default.htm*, *http://www.fda.gov/cder/guidance/index.htm*, or *http://www.fda.gov/cber/reading.htm*.

Dated: August 29, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–17597 Filed 9–2–05; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: Notice and request for comments.

SUMMARY: The Federal Emergency Management Agency, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed information collections. In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)), this notice seeks comments concerning information required by FEMA to amend or revise National Flood Insurance Program Maps to remove certain property from the 1-percent annual chance floodplain.

SUPPLEMENTARY INFORMATION. With the passage of the Flood Disaster Protection Act of 1973, an owner of a structure, with a federally backed mortgage, located in the 1-percent annual chance floodplain, was required to purchase federal flood insurance. This was in response to the escalating damage caused by flooding and the unavailability of flood insurance from commercial insurance companies. As part of this effort, FEMA mapped the 1-percent annual chance floodplain in communities. However, due to scale limitations, individual structures that may be above the base flood cannot always be shown as being out of the 1-percent annual chance floodplain. FEMA will issue a Letter of Map Amendment (LOMA) or a Letter of Map Revision—Based on Fill (LOMR–F) to waive the Federal requirement for flood insurance when data is submitted to show that the property or structure is ''reasonably safe from flooding'' and at or above the elevation of the base flood.

Collection of Information

Title: Right to Submit Technical or Scientific Data to Correct Mapping Deficiencies.

Type of Information Collection: Revision of a Currently Approved Collection.

OMB Number: 1660–0015.

Form Numbers: FEMA Forms 81–87, 81–87A, 81–87B.

Abstract: The certification forms (referred to as MT–1 series forms) are designed to assist requesters in gathering information that FEMA needs to determine whether a certain property is likely to be flooded during the flood event that has a 1-percent annual chance of being equaled or exceeded in any given year (base flood). FEMA Form 81–87, Property Information, describes the location of the property, what is being requested, and what data are required to support the request. FEMA Form 81–87A, Elevation Information, indicates what the Base (1-percent annual chance) Flood Elevation (BFE) for the property is, how the BFE was determined, the lowest ground elevation on the property, and/or the elevation of the lowest adjacent grade to any structures on the property. This information is required in order for FEMA to determine if the property that the requester would like removed from the SFHA FEMA Form 81–87B, Community Acknowledgment, requires that a community official certify that the request complies with minimum floodplain management criteria specified in 44 CFR 60.3, as per NFIP regulations 44 CFR 65.5(a)(4).

Estimated Total Annual Burden Hours: 57,300.

ANNUAL BURDEN HOURS

Project/activity (survey, form(s), focus group, etc.)	Number of respondents (A)	Frequency of responses (B)	Burden hours per respondent (C)	Annual responses (A × B)	Total annual burden hours (A × B × C)
81–87	18,272	Annual (1)	1.63	18,272	29,783
81–87A	18,272	Annual (1)	1.25	18,272	22,840
81–87B	3,389	Annual (1)	1.38	3,389	4,677
Total	39,933		4.26	39,933	57,300

Estimated Cost. Cost to respondents is estimated to be $1,325,597 annually, while the cost to the Federal Government is estimated to be $94,300 annually.

Comments: Written comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses. Comments should be received within 60 days of the date of this notice.

ADDRESSES: Interested persons should submit written comments to Chief, Records Management Section, Information Resources Management Branch, Information Technology