

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier A. Corbin

[Docket No. FDA-2007-D-0364] (formerly Docket No. 2007D-0080)

Guidance for Industry on Indexing Structured Product Labeling; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Indexing Structured Product Labeling." This guidance explains that the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER) will index structured product labeling (SPL) in the product labeling for human drug and biologic products. This guidance also makes recommendations to industry on how to submit input regarding the indexing information in the SPL.

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

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring MD 20993-0003, or the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance can also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800.

Submit written comments on the 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.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Laurie Burke, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6462, Silver Spring, MD 20993-0002, laurie.burke@fda.hhs.gov, or

Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Indexing Structured Product Labeling.” This guidance explains that CBER and CDER will index SPL in the product labeling for human drug and biological products. This guidance also makes recommendations to industry on how to submit input regarding the indexing information in the SPL.

A Health Level Seven (HL7) standard, SPL enables the electronic exchange of the content of labeling and other regulated product information using the extensible markup language. The SPL standard enables the inclusion of indexing elements with product labeling. These machine readable identifiers enable users with clinical decision support tools and electronic prescribing systems to rapidly search and sort product information found in product labeling. Indexing the content of labeling with SPL will greatly facilitate the

efficient communication of important drug information to the public, helping create a more robust nationwide system for promoting the safe and effective use of drugs.

After completing a 6-month pilot project evaluating how best to add indexing elements, FDA determined that the most efficient strategy is for FDA, not individual applicants, to index the SPL using a phased approach. We will index the pharmacological class during the first phase. We are adding the pharmacologic class first because: (1) It is important for the safe use of drugs; (2) it is necessary for making future indexing meaningful (e.g., drug interactions); and (3) this choice leverages existing FDA resources. After pharmacologic class, we will be seeking public input on which indexing elements should be added in future phases.

The guidance also recommends that applicants submit any questions regarding existing indexing, including any requests to add or revise an indexing element, to FDA by e-mail at *spl@fda.hhs.gov*. Inquiries and requests will be forwarded to the appropriate FDA personnel, who will consider them and make any appropriate change in the SPL.

In the **Federal Register** of March 19, 2007, FDA announced a draft version of this guidance entitled “Indexing Structured Product Labeling” (72 FR 12807). A number of comments were received, and FDA considered them carefully during finalization of the guidance. For example, applicants expressed a desire to recommend indexing terms to FDA; the guidance now provides advice on this topic. Applicants also indicated that they would like to see the indexing terms that FDA has selected prior to indexing. The guidance describes a high level process for sharing indexing terms before FDA actually indexes the SPL decision for a specific element, e.g., pharmacologic

class. The guidance also clarifies various points set forth in the draft guidance that the public suggested needed clarification. This guidance is being issued as a joint CDER-CBER guidance in preparation for CBER to implement SPL in the future.

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 indexing SPL. 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

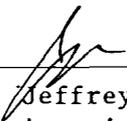
Comments on agency guidances are welcome at any time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm>, <http://www.fda.gov/cber/guidelines.htm>, or <http://www.fda.regulations>.

Dated: 5/23/08
May 23, 2008.



Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

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