Products." The May 2007 draft guidance gave interested persons an opportunity to submit comments through August 29, 2007. The agency is finalizing the guidance after considering comments received on the draft guidance. Minor changes were made to the draft guidance to update FDA Web site information.

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 a new process for making available to sponsors FDA guidance on how to design product-specific bioequivalence studies to support ANDAs. 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**) either electronic or written comments regarding the guidance. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

III. Electronic Access

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

Dated: June 3, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–14036 Filed 6–10–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0256]

Indexing Structured Product Labeling for Human Prescription Drug and Biological Products; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration's (FDA's) Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) are indexing certain categories of information in product labeling for use as terms to search repositories of approved prescription medical product structured product labeling (SPL). FDA has previously identified pharmacologic class as a top priority for indexing of product labeling information. FDA is now announcing that medical product indications is another category of product labeling information that the agency has identified as a high priority for indexing. CDER and CBER are announcing the establishment of a public docket to provide an opportunity for interested parties to share information, research, and ideas on the FDA indexing process.

DATES: Submit either electronic or written comments by August 10, 2010.

ADDRESSES: 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. All comments should be identified with the docket number found in the brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Colleen E. Brennan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6439, Silver Spring, MD 20993–0002, 301–796–2316; or Denise Sánchez, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

As part of the effort to advance medical informatics to support the safe use of medical products, CDER and CBER are using the SPL format to index labeling information for human prescription drug and biological products. SPL is a document markup standard approved by Health Level Seven adopted by FDA as a mechanism for exchanging product information by using extensible markup language. Indexing refers to the insertion of machine-readable tags that do not appear in actual printed labeling, but enable users with clinical decision support tools and electronic prescribing systems to rapidly search and sort product information. This is an important step toward the creation of a fully automated health information exchange system.

Indexed labeling can help prevent prescription errors and enhance the safe use of medical products. For example, among other benefits, the SPL indexing can enable a hospital's computer system to help detect that products prescribed by the hospital to treat a patient's injury do not adversely interact with other products that the patient is taking. It is important that this indexing be done consistently to enable comprehensive searches to find all relevant information, including appropriate synonyms.

In recent years, FDA pilot-tested the addition of SPL indexing to human prescription drug and biological product labeling. Based on that experience, feedback from industry, and feedback from other SPL users, FDA's approach will be to index product labeling information and link an indexed SPL file to the content of labeling SPL file available in the official SPL public access repository. Considering FDA's available resources, we have instituted a phased implementation of indexing for certain categories for all human prescription drug and biological product labeling. Indexing information on the pharmacologic class and indications categories of product labeling is being undertaken by the agency, as resources permit (see more information below). As the phased implementation proceeds, all human prescription drug and biological product labeling may be linked to certain key indexing.

For additional information, including the guidance for industry "Indexing Structured Product Labeling," refer to the FDA Data Standards Council Web page on SPL at *http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm*. FDA will update the Data Standards Council Web site to include all SPL indexing and their related terminologies as they are developed.

When the indexing of pharmacologic class and indications is complete, FDA intends to index other categories of product labeling information using a phased implementation process. The types and priority order of indexing of subsequent categories will be determined based on public input and agency priorities.

II. Indexing Pharmacologic Class

In June 2008, FDA issued the guidance for industry "Indexing Structured Product Labeling." This guidance states the agency's intention to index product labeling information, as resources permit, and identifies pharmacologic class as a top indexing priority. As part of its review and label

approval process, FDA identifies the established pharmacologic class for each approved medical product if appropriate. An established pharmacologic class is one that FDA has determined is scientifically valid and clinically meaningful according to the principles outlined in the guidance for industry and review staff "Labeling for Human Prescription Drugs and Biological Products—Determining Established Pharmacologic Class for Use in the Highlights of Prescribing Information," published in October 2009.

For SPL indexing, the established pharmacologic class is represented by an established pharmacologic class term or phrase. FDA also uses the Department of Veterans Affairs National Drug File Reference Terminology to identify other scientifically valid and clinically meaningful SPL indexing terms for each active ingredient that are representative of mechanism of action, physiologic effect, and chemical structure.

On the FDA Data Standards Council Web site, FDA has posted a Microsoft Excel spreadsheet containing a list of proposed established pharmacologic classes and indexing concepts completed to date for each active ingredient associated with approved human prescription drug and biological products.[1]

III. Indexing Indications Information

FDA has determined that another high priority for indexing of product labeling information, as resources permit, is the medical product indications category.

With indexing of indications, the goal is to determine terms or phrases that represent the recognized disease or condition, manifestation of a recognized disease or condition, or symptoms associated with a recognized disease or condition that accurately capture the approved indication appearing in the Indications section of labeling. The current intent is to index the basic indication concepts without the more specific usage and limitations of use information. Criteria are under development to determine the appropriate level of granularity and consistency in the choice of concepts indexed.

After consideration of existing alternatives including the National Library of Medicine's Clinical Observations Recording and Encoding (CORE) subset of Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT), FDA chose the Veterans Health Administration and Kaiser Permanente (VA/KP) Problem List subset of SNOMED CT as the terminology for SPL indexing of product labeling information on indication.[2]

SNOMED CT is a comprehensive clinical terminology that includes expressions for body structures, clinical findings, procedures, and hundreds of thousands of other clinical concepts. More information on SNOMED CT is available at *http://www.nlm.nih.gov/research/umls/Snomed/snomed_main.html*.

IV. Request for Comments

FDA is establishing an open docket for comments to obtain public input on the indexing process. Representatives of the human prescription drug and biological product industries, health care providers, and other health care professionals are particularly encouraged to participate and submit comments.

FDA is asking for comment on all aspects of indexing the content of labeling. In particular, FDA is asking for comments on the following:

1. FDA is currently indexing pharmacologic class and indications. When indexing of these categories is complete, FDA plans to index additional labeling information categories. For example, warnings and precautions, other adverse reactions, drug interactions, pediatric, or pregnancy information may be useful categories of information for future indexing. Other categories may also be identified. Please comment on the subsequent labeling categories that should be indexed by FDA as well as the priority order for indexing these categories.

2. For each indexing category, FDA will develop a series of principles to ensure the consistent assignment of indexing concepts. Please comment on the type of principles that may be useful for this task.

3. FDA chose the VA/KP Problem List subset of SNOMED CT as the indexing terminology for indications for the following reasons:

- The VA/KP Problem List is the named SPL data standard terminology for indexing the medical condition.[3]
- The subset represents conditions at a level of discreteness that are clinically relevant.

Please comment on the use of the VA/KP Problem List for the indexing of indications.

4. For indications, the degree of complexity indexed is limited by FDA's intention to first capture the main focus of the indication as a single existing concept using the 01312010 version of the SNOMED CT VA/KP Problem List subset. Additional indication modifiers found in approved product labeling such as disease severity or chronicity will not always be indexed. Please comment on this approach.

5. FDA will use the SPL standard to disseminate indexing information. Once entered into the SPL file, the indexed elements will be available for uploading into computer systems for sorting and other data manipulations. We believe this approach is more user friendly than the Microsoft Excel spreadsheet format we are currently using to showcase pharmacologic class on the Data Standards Web site. Please comment on this approach to make SPL indexing information available to interested parties.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Dated: June 7, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–14047 Filed 6–10–10; 8:45 am]

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[1] See *http://www.fda.gov/ForIndustry/DataStandards/StructuredProductfxsp0;Labeling/ucm162549.htm*.

[2] FDA News: *http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2006/ucm108642.htm*

[3] SNOMED CT VA/KP subset: *http://www.nlm.nih.gov/research/umls/Snomed/snomed_problem_list.html*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1576–N]

Medicare and Medicaid Programs; Procedure for Hospitals Seeking To Enter Into an Agreement With a Different Organ Procurement Organization Following an 1138(a)(2) Waiver

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.