POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

All records are stored on magnetic media.

RETRIEVABILITY:

All Medicare records are accessible by HIC number or alpha (name) search. This system supports both online and batch access.

SAFEGUARDS:

CMS has safeguards in place for authorized users and monitors such users to ensure against unauthorized use. Personnel having access to the system have been trained in the Privacy Act and information security requirements. Employees who maintain records in this system are instructed not to release data until the intended recipient agrees to implement appropriate management, operational and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems and to prevent unauthorized access.

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations include but are not limited to: The Privacy Act of 1974; the Federal Information Security Management Act of 2002; the Computer Fraud and Abuse Act of 1986; the Health Insurance Portability and Accountability Act of 1996; the E-Government Act of 2002, the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003, and the corresponding implementing regulations. OMB Circular A–130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources also applies. Federal, HHS, and CMS policies and standards include but are not limited to: All pertinent NIST publications; the HHS Automated Information Systems Security Handbook and the CMS Information Security Handbook.

RETENTION AND DISPOSAL:

• ''Records will be retained until an approved disposition authority is obtained from the National Archives and Records Administration.''

SYSTEM MANAGER AND ADDRESS:

Director, Survey and Certification Group, Center for Medicaid and State Operations, CMS, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

NOTIFICATION PROCEDURE:

For purpose of access, the subject individual should write to the system manager who will require the system name, health insurance claim number, address, date of birth, and sex, and for verification purposes, the subject individual's name (woman's maiden name, if applicable), and social security number (SSN). Furnishing the SSN is voluntary, but it may make searching for a record easier and prevent delay.

RECORD ACCESS PROCEDURE:

For purpose of access, use the same procedures outlined in Notification Procedures above. Requestors should also reasonably specify the record contents being sought. (These procedures are in accordance with department regulation 45 CFR 5b.5 (a)(2)).

CONTESTING RECORD PROCEDURES:

The subject individual should contact the system manager named above, and reasonably identify the record and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with department regulation 45 CFR 5b.7).

RECORD SOURCE CATEGORIES:

The data contained in these records are furnished by the individual, or in the case of some MSP situations, through third party contacts. There are cases, however, in which the identifying information is provided to the physician by the individual; the physician then adds the medical information and submits the bill to the carrier for payment. Updating information is also obtained from the Railroad Retirement Board, and the Master Beneficiary Record maintained by the Social Security Administration.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. E7–4889 Filed 3–16–07; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pediatric Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pediatric Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues. The committee also advises and makes recommendations to the Secretary of Health and Human Services under 21 CFR 50.54 and 45 CFR 46.407 on research involving children as subjects that is conducted or supported by the Department of Health and Human Services, when that research is also regulated by FDA.

Date and Time: The meeting will be held on April 11, 2007, from 4 p.m. to 6 p.m.

Location: Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Carlos Pena, Office of Science and Health Coordination, Office of the Commissioner (HF–33), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, rm. 14B–08), Rockville, MD 20857, 301–827–3340, e-mail: *Carlos.Pena@fda.hhs.gov* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 8732310001. Please call the Information Line for up to date information on this meeting.

Agenda: The Pediatric Advisory Committee will hear and discuss reports by the agency, as mandated in section 17 of the Best Pharmaceuticals for Children Act, on adverse event reports for fluvastatin (LESCOL) and octreotide (SANDOSTATIN). The committee will also receive updates to adverse event reports for orlistat (XENICAL) and oxybutynin (DITROPAN) which were requested by the Pediatric Advisory Committee when the reports were first presented.

FDA intends to make background material available to the public no later than 1 business day before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2007 and scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written

submissions may be made to the contact person on or before March 28, 2007. Oral presentations from the public will be scheduled between approximately 4 p.m. to 5 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before by March 20, 2007. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open pubic hearing session. The contact person will notify interested person regarding their request to speak by March 21, 2007.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please notify Carlos Pena at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 8, 2007.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E7–4877 Filed 3–16–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0080]

Draft 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 draft guidance for industry entitled ''Indexing Structured Product Labeling.'' This guidance explains that the Center for Drug Evaluation and Research (CDER) will index structured product labeling (SPL) in the product labeling for human drugs. This guidance also makes recommendations to industry on how to request a change to the indexing information in the SPL.

DATES: Submit written or electronic comments on the draft guidance by June 18, 2007. General comments on agency guidance documents are welcome at any time.

ADDRESSES: 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. Send one self-addressed adhesive label to assist that office in processing your requests. 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft 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*.

SUPPLEMENTARY INFORMATION:

I. Background

The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Indexing Structured Product Labeling.'' This guidance explains that FDA's CDER will index SPL in the product labeling for human drugs. This guidance also makes recommendations to industry on how to request a change to the indexing information in the SPL.

A Health Level Seven (HL7)[1] standard, SPL is used for electronically exchanging 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, such as clinical decision support tools and electronic prescribing systems, to rapidly search and sort product information found in product labels. Indexing the 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 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 draft guidance also recommends that applicants submit any questions regarding existing indexing, including any requests to add or revise an indexing element, to CDER (*spl@fda.hhs.gov*). Inquiries and requests will be forwarded to the appropriate FDA personnel who will consider them and make the appropriate change in the SPL.

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 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

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.

III. Electronic Access

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

[1] See *http://www.hl7.org.* (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)