FD–08–005.'' If you experience technical difficulties with your online submission you should contact Gladys Melendez-Bohler by telephone 301–827–7168 or by e-mail *gladys.melendez-bohler@fda.hhs.gov*.

Data and information included in the application will generally not be publicly available prior to the funding of the application. After funding has been awarded, data and information included in the application will be given confidential treatment to the extent permitted by the Freedom of Information Act (5 U.S.C. 552(b)) and FDA's implementing regulations (including 21 CFR Part 20 and §§ 20.61, 20.105, and 20.106). By accepting funding, the applicant agrees to allow FDA to publish specific information about the grant. Collecting information on Form SF424 (R&R) has been approved and assigned OMB control number 4040–0001.

C. Submission Dates and Times

The application submission receipt date is within 90 days after the date of the publication of the Funding Opportunity Announcement in the **Federal Register**. The application will be accepted electronically until the established receipt date.

On time submission requires that applications be successfully submitted to Grants.gov no later than 5 p.m local time (of the applicant's institution/organization).

D. Intergovernmental Review

The regulations issued under Executive Order 12372, Intergovernmental Review of Federal Program (45 CFR Part 100) do not apply.

E. Funding Restrictions

This agreement will be subject to all policies and requirements that govern the research grant programs of the PHS, including Provisions of 42 CFR Part 52 and 45 CFR Parts 74 and 92. All grants are subject to the terms and conditions, cost principles, and other considerations described in the January 6, 2007, HHS Grants Policy Statement that are applicable based on your recipient type and the purpose of this award. This includes any requirements in Parts I and II (available at *http://www.hhs.gov/grantsnet/adminis/gpd/index.htm*).

Although consistent with the HHS Grants Policy Statement (GPS), any applicable statutory or regulatory requirements, including 45 CFR parts 74 or 92, directly apply to this award apart from any coverage in the HHS GPS.

V. Agency Contacts

For issues regarding the programmatic aspects of this notice: Mark Wirtz, Center for Food Safety and Applied Nutrition (HFS–002), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2001, e-mail: *mark.wirtz@fda.hhs.gov*. For issues regarding the administrative and financial management aspects of this notice contact, Gladys Melendez-Bohler at 301–827–7168 or by e-mail at *gladys.melendez-Bohler@fda.hhs.gov*.

Dated: May 23, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–12159 Filed 5–30–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[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: May 23, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–12158 Filed 5–30–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Host Interactions with Bacterial Pathogens.

Date: June 12, 2008.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Latham Hotel, 3000 M Street, NW., Washington, DC 20007.

Contact Person: Richard G. Kostriken, PhD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3192, MSC 7808, Bethesda, MD 20892, 301–402–4454, *kostrikr@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; CASE and KNOD SRG Member Conflict Panel.

Date: June 16, 2008.

Time: 10 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Fungai F. Chanetsa, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3135, MSC 7770, Bethesda, MD 20892, 301–435–1262, *chanetsaf@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review, Special Emphasis Panel, Urology Overflow Applications.

Date: June 17, 2008.

Time: 4 p.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Ryan G. Morris, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4205, MSC 7814, Bethesda, MD 20892, 301–435–1501, *morrisr@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review, Special Emphasis Panel, Neurobiophysical Topics.

Date: June 18, 2008.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Mary Custer, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4148, MSC 7850, Bethesda, MD 20892–7850, (301) 435–1164, *custerm@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review, Special Emphasis Panel, Fungal Pathogens.

Date: June 23, 2008.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.