Type of application form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Business Plan (Non-Competing)	1,034	1	1,034	2.0	2,068
Services Provided	1,034	1	1,034	1.0	1,034
Sites Listing	1,034	1	1,034	1.0	1,034
Other Site Activities	700	1	700	0.5	350
Change In Scope (CIS) Site Add Checklist	300	1	300	1.0	300
CIS Site Delete Checklist	200	1	200	1.0	200
CIS Relocation Checklist	200	1	200	1.5	300
CIS Service Add Checklist	100	1	200	1.0	200
CIS Service Delete Checklist	100	1	100	1.0	100
Board Member Characteristics	1,034	1	1,034	1.0	1,034
Request for Waiver of Governance Requirements	150	1	150	1.0	150
Health Center Affiliation Certification	250	1	250	1.0	250
Need for Assistance	900	1	900	3.0	2,700
Emergency Preparedness Form	1,034	1	1,034	1.0	1,034
Points of Contact	800	1	800	0.5	400
EHR Readiness Checklist	250	1	250	1.0	250
Environmental Information and Documentation (EID)	400	1	400	2.0	800
Capital Improvement/Investment Proposal Cover Page	700	1	700	1.0	700
Assurances	900	1	900	.5	450
Capital Improvement/Investment Project Cover	700	1	700	1.0	700
Capital Improvement/Investment Project Impact	700	1	700	.5	350
Equipment List	900	1	900	1.0	900
Other Requirements for Sites	900	1	900	.5	450
Total	1,138	1	23,976		40,161

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974. Please direct all correspondence to the "attention of the desk officer for HRSA."

Dated: June 7, 2010.

Sahira Rafiullah,

Director, Division of Policy and Information Coordination.

[FR Doc. 2010–14108 Filed 6–10–10; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0433] (formerly Docket No. 2007D–0169)

Guidance for Industry on Bioequivalence Recommendations for Specific Products; 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 "Bioequivalence Recommendations for Specific Products." This guidance describes a new process for making available recommendations on how to design product-specific bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs). Under this process, applicants planning to carry out such studies in support of their ANDAs are able to access BE study guidance on the FDA Web site. FDA believes that making this information available on the Internet will streamline the guidance process and will provide a meaningful opportunity for the public to consider and comment on product-specific BE study recommendations.

DATES: Submit either electronic or written comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance 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.

FOR FURTHER INFORMATION CONTACT: Doan T. Nguyen, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9314.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Bioequivalence Recommendations for Specific Products." This guidance describes a new process for making available recommendations on how to design product-specific BE studies to support ANDAs. Under this process, draft and final BE recommendations are posted on FDA's Web site (*http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, Individual Product Bioequivalence Recommendations) and announced periodically in the **Federal Register**. For draft BE recommendations, the **Federal Register** notice will identify a comment period. The public is encouraged to submit comments on the draft BE recommendations, and the agency will consider received comments in developing final BE recommendations. FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and provide an opportunity for the public to consider and comment on those recommendations.

In the **Federal Register** of May 31, 2007 (72 FR 30388), FDA announced the availability of a draft version of this guidance entitled "Bioequivalence Recommendations for Specific

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