

ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

**Robert Sargis,**

*Reports Clearance Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0422]

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Information From United States Firms and Processors That Export to the European Community

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Information From United States Firms and Processors That Export to the European Community" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3793.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of November 23, 2010 (75 FR 71444), the Agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0320. The approval expires on February 28, 2014. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: May 4, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-11360 Filed 5-9-11; 8:45 am]

BILLING CODE 4160-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0631]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by June 9, 2011.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, *Attn:* FDA Desk Officer, FAX: 202-395-7285, or e-mailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0638. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3792, [Elizabeth.Berbakos@fda.hhs.gov](mailto:Elizabeth.Berbakos@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Guidance for Industry on Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices—(OMB Control Number 0910-0638)—Extension

The Food and Drug Administration Amendments Act of 2007 (FDAAA) includes a requirement that FDA identify and periodically update susceptibility test interpretive criteria for antibacterial drug products and make those findings publicly available. As a result of this provision, the guidance explains the importance of making available to health care providers the most current information regarding susceptibility test interpretive criteria for antibacterial drug products. To address concerns about antibacterial drug product labeling with out-of-date information on susceptibility test interpretive criteria, quality control parameters, and susceptibility test methods, the guidance describes procedures for FDA, applications holders, and antimicrobial susceptibility testing device manufacturers to ensure that updated susceptibility test information is available to health care providers. Where appropriate, FDA will identify susceptibility test interpretive criteria, quality control parameters, and susceptibility test methods by recognizing annually, in a **Federal Register** notice, standards developed by one or more nationally or internationally recognized standard development organizations. The FDA recognized standards will be available to application holders of approved antibacterial drug products for updating their product labeling.

Application holders can use one of the following approaches to meet their responsibilities to update their product labeling under the guidance and FDA regulations: Submit a labeling supplement that relies upon a standard recognized by FDA in a **Federal Register** notice or submit a labeling supplement that includes data supporting a proposed change to the microbiology information in the labeling. In addition, application holders should include in their annual report an assessment of whether the information in the "Microbiology" subsection of their product labeling is current or whether changes are needed. This information collection is already approved by OMB under control number 0910-0572 (the requirement in 21 CFR 201.56(a)(2) to update labeling when new information becomes available that causes the labeling to become inaccurate, false, or misleading) and control number 0910-0001 (the requirement in 21 CFR

314.70(b)(2)(v) to submit labeling supplements for certain changes in the product's labeling and the requirement in 21 CFR 314.81(b)(2)(i) to include in the annual report a brief summary of significant new information from the previous year that might affect the labeling of the drug product).

In addition, under the guidance, if the information in the applicant's product labeling differs from the standards recognized by FDA in the **Federal Register** notice, and the applicant believes that changes to the labeling are not needed, the applicant should provide written justification to FDA why the recognized standard does not apply to its drug product and why

changes are not needed to the "Microbiology" subsection of the product's labeling. This justification should be submitted as general correspondence to the product's application, and a statement indicating that no change is currently needed and the supporting justification should be included in the annual report. Based on our knowledge of the need to update information on susceptibility test interpretive criteria, susceptibility test methods, and quality control parameters in the labeling for systemic antibacterial drug products for human use, and our experience with the FDAAA requirement and the guidance recommendations during the past 16

months, we estimate that, annually, approximately two applicants will submit the written justification described previously and in the guidance, and that each justification will take approximately 16 hours to prepare and submit to FDA as general correspondence and as part of the annual report.

In the **Federal Register** of December 23, 2010 (75 FR 80823), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Justification Submitted as General Correspondence and in the Annual Report .....	2	1	2	16	32
Total .....	.....	.....	.....	.....	32

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: May 3, 2011.  
**Leslie Kux**,  
*Acting Assistant Commissioner for Policy.*  
 [FR Doc. 2011-11359 Filed 5-9-11; 8:45 am]  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2011-N-0326]

**Biologics Price Competition and Innovation Act of 2009; Options for a User Fee Program for Biosimilar and Interchangeable Biological Product Applications for Fiscal Years 2013 Through 2017; Request for Comments**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is issuing this document to request comments relating to the development of a user fee program for biosimilar and interchangeable biological product (351(k)) applications submitted under the Public Health Service Act (PHS Act). FDA is requesting input on the identified principles for development of a 351(k) user fee program, FDA's proposed structure for a 351(k) user fee program that would adhere to these

principles, and performance goals for this program. FDA plans to review the comments submitted to the docket, hold meetings with public stakeholders, and hold industry stakeholder meetings to develop proposed recommendations for a user fee program for 351(k) applications for fiscal years (FYs) 2013 through 2017.

**DATES:** Submit either electronic or written comments by June 9, 2011. Submit notification of interest in participating in public stakeholder meetings or industry stakeholder meetings on or before June 3, 2011.

**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. Public and industry stakeholders who have not yet notified FDA of their interest in participating in these meetings should e-mail complete contact information to [BiosimilarsUserFeeProgram@fda.hhs.gov](mailto:BiosimilarsUserFeeProgram@fda.hhs.gov). (See sections VI.B and VI.C of this document for additional information.)

**FOR FURTHER INFORMATION CONTACT:**

Sunanda Bahl, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1168, Silver Spring, MD 20993-0002, 301-

796-3584, FAX: 301-847-8443, *e-mail:* [sunanda.bahl@fda.hhs.gov](mailto:sunanda.bahl@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

On March 23, 2010, President Obama signed into law the Affordable Care Act (Pub. L. 111-148). The Affordable Care Act contains a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCI Act) that amends the PHS Act and other statutes to create an abbreviated approval pathway for biological products shown to be highly similar (biosimilar) to, or interchangeable with, an FDA-licensed reference biological product. (See sections 7001 through 7003 of the Affordable Care Act.) Section 351(k) of the PHS Act (42 U.S.C. 262(k)), added by the BPCI Act, allows a company to submit an application for licensure of a biosimilar or interchangeable biological product.

The BPCI Act amends section 735 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379g) to include 351(k) applications in the definition of "human drug application" for the purposes of the prescription drug user fee provisions. (See section 7002(f)(3)(A) of the Affordable Care Act.) Accordingly, under section 736 of the FD&C Act (21 U.S.C. 379h), the fee for a biologics license application (BLA) is currently the same regardless of whether the application is submitted