

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]  
**BILLING CODE 4160-01-P**

**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:**

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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

under the new 351(k) approval pathway or the preexisting 351(a) approval pathway.

The authority conferred by the FD&C Act's prescription drug user fee provisions expires in September 2012. The BPCI Act directs FDA to develop recommendations for a user fee program for 351(k) applications for FYs 2013 through 2017. (See section 7002(f)(1) of the Affordable Care Act.) In developing recommendations for a biosimilar and interchangeable biological products user fee program, FDA is required to consult with a range of groups, including scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups, and regulated industry. The recommendations must be presented to Congress by January 15, 2012. (See section 7002(f)(1) of the Affordable Care Act.)

Developing a user fee program for 351(k) applications presents unique challenges as compared to other medical product user fee programs. One key consideration in developing a user fee program is the state of the regulated industry. For example, when the Prescription Drug User Fee Act (PDUFA) program was first implemented in FY 1993, the biopharmaceutical industry was relatively mature. FDA had a record of more than 2,000 drug and biological products already on the market, more than 200 establishments were involved in the manufacturing of these products, and approximately 120 new drug marketing applications were submitted each year for FDA review. The number of participants in the industry and the volume of anticipated annual applications allowed FDA to generate significant revenue from user fees tied to marketing application submissions and currently marketed products (product and establishment fees). In contrast, given that the biosimilar and interchangeable biological product approval pathway did not exist prior to March 2010, the biosimilar and interchangeable biological product market is just forming. Although FDA has met with sponsors who are interested in developing biosimilar and interchangeable biological products, no products have been approved for marketing under section 351(k) of the PHS Act. As such, although the PDUFA program is a useful model, FDA believes that a user fee program for 351(k) applications will need to include different elements to ensure an equitable program that generates adequate revenue.

In this document, FDA describes the principles it proposes to use to develop

a biosimilars user fee program, a proposed structure for the program based on these principles, and proposed performance goals. FDA is requesting public comment on each of these proposals, and is also posing several questions for public input on some unresolved issues associated with developing performance goals for this new user fee program.

## II. Principles for Development of a Biosimilars User Fee Program

FDA proposes to develop recommendations for the 351(k) user fee program that are guided by a set of key principles to support the development of a fair and adequate initial user fee program.<sup>1</sup> These proposed principles are based on FDA's prior experience with elements that foster strong and successful user fee programs, as well as comments submitted to the docket by external stakeholders. FDA solicits comment on these proposed principles. The proposed principles are:

(1) Biosimilar and interchangeable biologics represent a critical public health benefit to patients, with the potential to offer life-saving or life-altering benefits at reduced costs to the patient. FDA needs sufficient review capacity to prevent unnecessary delays in the development and approval of these products.

(2) At least for the initial 5-year authorization of the 351(k) user fee program, 351(k) user fees should remain comparable to 351(a) user fees. This aligns with the PDUFA standard for assessing human drug application fees for applications for which clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness are required for approval. That is, under PDUFA, the fee for a new drug application (NDA) that is submitted under section 505(b)(2) of the FD&C Act (21 U.S.C. 355(b)(2)) and that requires clinical data is the same as the fee for an NDA submitted under section 505(b) that requires clinical data for approval, even though the 505(b)(2) approval pathway allows an applicant to rely on studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use. FDA believes a similar approach is appropriate for applications for biosimilar products because, at least initially, review to determine biosimilarity or interchangeability of a proposed product in a 351(k) application is expected to be

comparably complex, technically demanding, and resource-intensive as review of a proposed 351(a) application. For example, characterizing biological products for the purpose of determining biosimilarity or interchangeability is challenging because the molecules of biological products tend to be much larger and have a far more complex spatial structure than small-molecule drugs. However, FDA does not expect that review of the 351(k) applications will require more resources than review of 351(a) applications. Therefore, the level of user fees for biosimilars should not exceed the level of 351(a) user fees.

(3) The 351(k) user fee program should provide funding to support activities that occur early in the biosimilar and interchangeable product development cycle. Given that the approval pathway for biosimilar and interchangeable biological products is new, FDA services are most critical for continued and successful development of biosimilar and interchangeable biological products during the investigational stage prior to submission of a marketing application. To date, most of FDA's work on biosimilars has been focused on development of regulatory standards, policy, and consultations with 351(k) sponsors to support product development leading to a marketing application. As a result, in developing an effective 351(k) user fee program, FDA should consider fee structures that fund critical activities that support submission of a marketing application.

(4) Innovator biologics represent a critical public health benefit to patients, often offering life-saving or life-altering therapies to treat previously unmet medical needs. The same expert scientific teams that conduct FDA's review of 351(a) applications will typically be involved in the review of 351(k) applications. The 351(k) user fee program should ensure adequate resources for the review of 351(k) applications, so that critical resources for 351(a) review are not redirected from innovator drug review to biosimilar products. Applications submitted under both section 351(a) and section 351(k) need adequate resourcing to ensure the best health outcomes for U.S. patients and fairness to all industry sponsors.

## III. Proposal for 351(k) User Fee Program for FYs 2013 Through 2017

FDA believes the proposed structure for a user fee program described in this section adheres to the proposed principles identified in section II of this document. The proposed structure would ensure sound funding for development of the scientific,

<sup>1</sup> As we expect the program to be reevaluated and reauthorized periodically as are all of FDA's other medical product user fee programs, our focus here is on the initial program.

regulatory, and policy infrastructure necessary for review of 351(k) applications, including resources for critical development-phase FDA consultation and review work, while charging no more for review of a 351(k) application than would be paid by applicants seeking review of a 351(a) marketing application. The level and timing of the proposed fee funding is also expected to minimize the risk of redirection of 351(a) review resources to biosimilars review work.

FDA's proposed structure for a 351(k) user fee program has some features that would be similar to the current PDUFA structure. First, because FDA expects that marketing application review, preapproval facility inspections, and safety issues will be comparably complex for 351(k) and 351(a) applications, for the initial 5-year authorization, the Agency proposes to maintain the PDUFA fee levels for 351(k) marketing applications, manufacturing establishments, and products. However, the Agency proposes to modify this structure to provide resources in the near-term because, as noted in section I of this document, there is no existing inventory of marketed products that would generate fees.

Sponsors are currently submitting requests for FDA meetings and consultations during the biosimilar product development phase. Given that sponsors have limited experience utilizing the novel 351(k) pathway, FDA expects that sponsors will continue to require significant advice and support throughout this phase. As a result, the Agency is proposing a 351(k) user fee structure that would shift payment for FDA review to the earlier stage of development where FDA activities currently are in greatest demand and increased review capacity is needed.

The proposed 351(k) user fee program would consist of the following:

For an Application in the Pre-market Phases

- *Biosimilar Product Development fee*, paid upon submission of an investigational new drug application (IND) and annually thereafter for a biosimilar or interchangeable product (molecule) under active development that is intended for submission in a single 351(k) marketing application.

- *351(k) Marketing Application fee*, paid for each submitted 351(k) marketing application. This fee would be set equal to a 351(a) marketing application fee, less the sum of all of the previously paid annual Biosimilar Product Development fees associated

with the biosimilar product that is the subject of the 351(k) application.

For Marketed 351(k) Products, the Annual Fees Would Include

- *Establishment fee*, paid annually for each biosimilar and interchangeable biological product establishment listed in an approved 351(k) application. The establishment fee is assessed for each biosimilar and interchangeable biological product that is assessed a product fee—unless the establishment listed in the application does not manufacture the product during the FY.

- *Product fee*, paid annually for each eligible approved biosimilar and interchangeable biological product.

These fees are described in more detail. (See sections III.A and B.)

#### A. Description of Proposed Fees

##### 1. Biosimilar Product Development Fee

FDA proposes an annual 351(k) Biosimilar Product Development fee for each distinct biosimilar or interchangeable product (molecule) under active development. The sponsor would pay this fee at IND submission and annually thereafter for the duration of the active development phase. The sponsor would be required to declare that the development program is intended to support a 351(k) marketing application upon IND submission. During the development phase, if the sponsor changes the approval pathway from 351(k) to another, such as the 351(a) approval pathway, then the sponsor would stop paying the Biosimilar Product Development fee. Similarly, if a sponsor changes the development program for an existing IND from the 351(a) pathway to the 351(k) pathway, the sponsor would be required to begin paying the Biosimilar Product Development fee. Failure to pay the Biosimilar Product Development fee on initial IND submission or annually as required would result in the IND being placed on Full Clinical Hold. When the applicant submits the associated 351(k) marketing application, the sum of the previously paid annual Biosimilar Product Development fees would be deducted from the 351(k) marketing application fee.

This annual Biosimilar Product Development fee would support the ongoing scientific, technical, and other regulatory activities associated with 351(k) biosimilar development, including milestone meetings and the application data reviews required to provide advice for the next steps in development. These fees are essential to enable the staffing capacity to handle the workload associated with activities

that support 351(k) product development programs. FDA estimates that the annual activities in this phase may be comparable to, or greater than, 351(a) IND application activities. These activities can include FDA review of study protocols; review of clinical, safety and other data; and providing sponsors with timely feedback and advice for their 351(k) development program. FDA anticipates that the FY 2013 annual Biosimilar Product Development fee amount would be on the order of \$150,000.

##### 2. 351(k) Marketing Application Fee

FDA estimates that the cost of reviewing a 351(k) marketing application will be comparable to the cost of reviewing a 351(a) marketing application. FDA therefore proposes to set the marketing application fee for a 351(k) submission equal to that of a 351(a) submission. The feedback and consultation that FDA expects to provide for active 351(k) INDs is expected to improve the efficiency of the 351(k) product development process and the quality of submitted 351(k) marketing applications. Therefore, FDA considers the deduction of the Biosimilar Product Development fee payments from the associated marketing application fee payment is a reasonable approach to shift resources forward to the point in development where FDA review is currently being sought by sponsors. When a 351(k) marketing application is submitted, the applicant would pay the 351(k) application fee less the sum of any associated paid annual Biosimilar Product Development fees. For example, if the IND sponsor paid a total of \$450,000 in Biosimilar Product Development annual fees, upon submission of the 351(k) marketing application, the applicant would pay the prevailing 351(k) marketing application fee (set equal to the 351(a) marketing application fee) less \$450,000.

##### 3. Annual Establishment and Product Fees for Marketed 351(k) Products

Because the complexity and level of effort required for FDA oversight of manufacturing and postmarket safety issues for products licensed under 351(k) is expected to be comparable to that required for products licensed under 351(a), FDA also proposes setting the establishment and product fee rates equal to the comparable PDUFA rates for any FY. FDA anticipates a modest level of funding from these sources because only biosimilar biological products already approved for marketing would be subject to these fees.

*B. Summary of Proposed 351(k) User Fee Program*

The intent of the proposed 351(k) user fee program is to provide FDA with

adequate funding throughout each stage in the development of a biosimilar or interchangeable biological product, ensuring efficiency in FDA's review and approval of these important therapies

without compromising review quality or approval standards. Table 1 of this document contains a summary of the proposed recommendations for the 351(k) user fee program.

TABLE 1—PROPOSED 351(k) USER FEE PROGRAM

| Fee category                        | Fee administration   | Estimated fee rates for FY 2013   |
|-------------------------------------|--|---|
| Pre 351(k) Market Approval Phase    |  |   |
| Biosimilar Product Development Fee. | Annual for each 351(k) IND, for duration of IND phase.                   | Based on the annual estimated cost of IND activities per year per IND. Estimated to be \$150,000.     |
| Application Fee .....               | For each 351(k) marketing application at time of application submission. | Set equal to PDUFA original NDA/BLA fee, less sum of payments of Biosimilar Product Development fees. |
| Marketed 351(k) Applications        |  |   |
| Establishment Fee .....             | Annual .....   | Set equal to PDUFA establishment fee.   |
| Product Fee .....                   | Annual .....   | Set equal to PDUFA product fee.   |

**IV. Proposed Performance Goals for 351(k) Applications for FYs 2013 Through 2017**

Under section 351(k)(7) of the PHS Act, a 351(k) application may not be submitted to the Secretary of Health and Human Services (the Secretary) until 4 years after the reference product was first licensed under section 351(a); however, the Secretary may not make approval of a 351(k) application effective until 12 years after the reference product was first licensed. Accordingly, in proposing performance goals for 351(k) applications for FYs 2013 through 2017, FDA must take into account the fact that two different categories of 351(k) applications may be submitted. In the first category are applications that are submitted 10 or more years after the date of first licensure of the reference product. Such applications would be eligible for approval in 2 years or less, depending on the relevant filing dates. For these applications, performance goals similar to those for 351(a) applications may be appropriate. Like the initial PDUFA review performance goals, FDA is proposing that the goals be phased in over the first 5 years of the program so that an increasing percentage of applications would be expected to be reviewed within the goal each year.

In the second category are applications submitted between 4 and 10 years after the date of first licensure of the reference product. Under section 351(k)(7) of the PHS Act, such applications would not be eligible for approval for more than 2 years and perhaps for as long as 8 years. For this second category of applications, FDA is concerned about committing resources to meet performance goals that might ready an application for approval years

before it could be approved, necessitating updating of the application, new reviews, and new inspections of facilities shortly before the application becomes eligible for approval under the section 351(k)(7). Accordingly, FDA is proposing performance goals for applications in the first category and soliciting public input on several questions relating to establishing performance goals for applications in the second category.

For 351(k) applications that are submitted 10 or more years after the date of first licensure of the reference product, FDA recommends the following proposed review performance goals for FYs 2013 through 2017:

*FY 2013*

- For applications requesting a biosimilarity determination, FDA proposes to review and act on 50 percent of original 351(k) submissions within 10 months of the 60-day filing date.
- For applications requesting an interchangeability determination, FDA proposes to review and act on 50 percent of original 351(k) submissions for interchangeability determination within 10 months of the 60-day filing date.
- For applications requesting a biosimilarity determination, FDA proposes to review and act on 50 percent of 351(k) resubmissions in response to a complete response action within 6 months of receipt.
- For applications requesting an interchangeability determination, FDA proposes to review and act on 50 percent of 351(k) resubmissions in response to a complete response action within 6 months of receipt.

*FY 2014*

- For applications requesting a biosimilarity determination, FDA proposes to review and act on 60 percent of original 351(k) submissions within 10 months of the 60-day filing date.
- For applications requesting an interchangeability determination, FDA proposes to review and act on 60 percent of original 351(k) submissions for interchangeability determination within 10 months of the 60-day filing date.
- For applications requesting a biosimilarity determination, FDA proposes to review and act on 60 percent of 351(k) resubmissions in response to a complete response action within 6 months of receipt.
- For applications requesting an interchangeability determination, FDA proposes to review and act on 60 percent of 351(k) resubmissions in response to a complete response action within 6 months of receipt.

*FY 2015*

- For applications requesting a biosimilarity determination, FDA proposes to review and act on 70 percent of original 351(k) submissions within 10 months of the 60-day filing date.
- For applications requesting an interchangeability determination, FDA proposes to review and act on 70 percent of original 351(k) submissions for interchangeability determination within 10 months of the 60-day filing date.
- For applications requesting a biosimilarity determination, FDA proposes to review and act on 70 percent of 351(k) resubmissions in response to a complete response action within 6 months of receipt.

- For applications requesting an interchangeability determination, FDA proposes to review and act on 70 percent of 351(k) resubmissions in response to a complete response action within 6 months of receipt.

#### *FY 2016*

- For applications requesting a biosimilarity determination, FDA proposes to review and act on 80 percent of original 351(k) submissions within 10 months of the 60-day filing date.
- For applications requesting an interchangeability determination, FDA proposes to review and act on 80 percent of original 351(k) submissions for interchangeability determination within 10 months of the 60-day filing date.
- For applications requesting a biosimilarity determination, FDA proposes to review and act on 80 percent of 351(k) resubmissions in response to a complete response action within 6 months of receipt.
- For applications requesting an interchangeability determination, FDA proposes to review and act on 80 percent of 351(k) resubmissions in response to a complete response action within 6 months of receipt.

#### *FY 2017*

- For applications requesting a biosimilarity determination, FDA proposes to review and act on 90 percent of original 351(k) submissions within 10 months of the 60-day filing date.
- For applications requesting an interchangeability determination, FDA proposes to review and act on 90 percent of original 351(k) submissions for interchangeability determination within 10 months of the 60-day filing date.
- For applications requesting a biosimilarity determination, FDA proposes to review and act on 90 percent of 351(k) resubmissions in response to a complete response action within 6 months of receipt.
- For applications requesting an interchangeability determination, FDA proposes to review and act on 90 percent of 351(k) resubmissions in response to a complete response action within 6 months of receipt.

To help the Agency develop performance goals for 351(k) applications that are submitted earlier than 10 years after first licensure of the reference product (*i.e.*, between year four and year ten), FDA requests comment on the following questions:

*Question IV.1:* What factors should the Agency consider in determining

appropriate performance goals for 351(k) applications that are filed earlier than 2 years prior to the date on which a 351(k) application would be eligible for approval (*i.e.*, 12 years after the date of first licensure of the reference product)? For example, how should the Agency address issues relating to review of critical quality attributes of the 351(k) product, technological developments, facility changes, and other issues that arise during the period of time between the filing of a 351(k) application (as early as 4 years after the date of first licensure of the reference product) and the date on which a 351(k) application would be eligible for approval (12 years after the date of first licensure of the reference product)?

*Question IV.2:* How should the performance goals take into account readiness for inspection? For example, should the performance goal (or user fee) structure take into account such factors as whether the product that is the subject of a 351(k) is already in commercial production for sale in another country? In such a case, if the sponsor proposes to use the same manufacturing facility for the 351(k) product, FDA could conduct an inspection at the facility and actually observe the production process. If the product is not being produced in another country, there may not be a facility ready for preapproval inspection, or even built yet. How should the performance goals take this into account?

*Question IV.3:* What other factors relating to the unique characteristics of the 351(k) approval pathway should the Agency consider when setting performance goals for 351(k) applications?

## **V. Stakeholder Meetings**

### *A. Public Stakeholder Meetings*

In the **Federal Register** of December 8, 2010 (75 FR 76472) (December 2010 notice), FDA issued a notice to request that public stakeholders, including patient and consumer advocacy groups, health care professionals, and scientific and academic experts, notify FDA of their intent to participate in consultation meetings related to the development of recommendations for a user fee program for biosimilar and interchangeable biological product applications. Public stakeholders who identified themselves in response to the December 2010 notice will be notified and invited to participate in future public stakeholder meetings that will be held over the same period when FDA is holding industry stakeholder meetings. (See section V.B of this document.) FDA

regulatory policy issues are beyond the scope of the proposed stakeholder discussions. Accordingly, stakeholder presentations and discussions will focus on the structure of the 351(k) user fee program, and not policy issues.

### *B. Industry Stakeholder Meetings*

The BPCI Act requires FDA to consult with “regulated industry” in developing recommendations for the 351(k) user fee program. Acknowledging the nascent state of the biosimilar biologics industry, FDA proposes to hold a series of industry stakeholder meetings to comply with this requirement.

Given that no approval pathway for biosimilar biological products existed prior to the BPCI Act, it is not clear which companies comprise “regulated industry” for biosimilar and interchangeable biological products. Accordingly, in the **Federal Register** document that announced the November 2 and 3, 2010, public hearing (November 2010 public hearing document) on the implementation of the BPCI Act, FDA sought comments relating to user fees and requested that those who submitted comments identify companies that would be affected by a 351(k) user fee program, as well as industry associations representing such companies. (See 75 FR 61497, October 5, 2010.) Based on comments submitted to the docket, FDA anticipates that companies that principally manufacture innovator drugs and companies that principally manufacture generic drugs will pursue biosimilar and interchangeable product development programs. Given the potential competing interests of the affected stakeholders, and given that no industry association exists to expressly represent the interests of 351(k) sponsors, FDA concludes that it will need to follow a different process for the 351(k) user fee program than for its other medical product user fee programs.

Specifically, FDA proposes to conduct a series of industry-stakeholder meetings over a period of 2 to 3 months in 2011, with the hope that this process will lead to a package of proposed recommendations with which all parties can align. All industry associations who have expressed interest, and individual industry sponsors who have identified their interest and intention to develop biosimilar biological products, will be invited to participate in the industry-stakeholder meetings. The industry stakeholder meetings will address the following:

- Review and discussion of key principles and criteria for design of a fair and adequate 351(k) user fee program.

- Review and discussion of FDA's proposed 351(k) user fee program structure and any alternative structures submitted to the public docket in response to this document that would also meet the key design principles and criteria.

- Review and discussion of FDA's proposed performance goals for 351(k) applications. FDA will review and analyze the industry stakeholder input obtained through this process. FDA will take this information into account, as well as information obtained from public stakeholder consultation meetings, in developing the proposed set of recommendations that will be presented to Congressional Committee staff, published in the **Federal Register** for public review and comment, and presented at a public meeting to obtain public input. After the public meeting, the proposed recommendations would be revised as necessary before transmittal to Congress by January 15, 2012.

## VI. Next Steps

### A. 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.

FDA encourages members of the public to submit comments to the docket on the following topics:

*Question VI.1:* FDA-proposed principles for a fair and adequate 351(k) user fee program (section II of this document),

*Question VI.2:* FDA-proposed structure for a 351(k) user fee program that aligns with these principles (section III of this document), and

*Question VI.3:* FDA-proposed performance goals for a 351(k) user fee program for FYs 2013 through 2017 (section IV of this document).

FDA also encourages the public to submit comments to the docket concerning any potential alternative 351(k) user fee structures that would align with the proposed principles. When you submit comments to the docket, identify the section of this document and the number of each question you address. FDA plans to review the comments submitted to the docket, hold consultation meetings with

public stakeholder groups, and hold industry stakeholder meetings, to refine the proposed recommendations for a 351(k) user fee program for FYs 2013 through 2017.

### B. Public Stakeholder Identification

Public stakeholders who have not yet notified FDA that they wish to participate in these consultation meetings should notify FDA by e-mail to [BiosimilarsUserFeeProgram@fda.hhs.gov](mailto:BiosimilarsUserFeeProgram@fda.hhs.gov) on or before June 3, 2011. Your e-mail should contain complete contact information, including name, title, organization affiliation, address, e-mail address, telephone number, and notice of any special accommodations required because of disability. Stakeholders will receive confirmation and additional information about the first meeting once FDA receives their notification.

### C. Industry Stakeholder Identification

FDA is requesting that industry stakeholders, including industry associations with relevant interests and individual companies with ongoing efforts or interest in developing biosimilar and interchangeable biological products, identify their interest in participating in industry stakeholder meetings. The purpose of these industry stakeholder meetings is to hold a series of discussions to develop proposed recommendations for a user fee program for biosimilar and interchangeable biological product applications for FYs 2013 through 2017.

If you have not yet notified FDA that you are a company or trade association that would be affected by a 351(k) user fee program, please provide notification by e-mail to

[BiosimilarsUserFeeProgram@fda.hhs.gov](mailto:BiosimilarsUserFeeProgram@fda.hhs.gov) on or before June 3, 2011. Your e-mail should contain complete contact information, including name, title, organization affiliation, address, e-mail address, telephone number, and notice of any special accommodations required because of disability.

## VII. Additional Information on the BPCI Act

There are several sources of information on FDA's Web site that may serve as useful resources for stakeholders intending to participate in consultation meetings:

- The **Federal Register** document that announced the November 2010, public hearing and requested public comments is available at <http://edocket.access.gpo.gov/2010/pdf/2010-24853.pdf>. (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**.)

- Comments submitted in response to the November 2010 public hearing document can be found at <http://www.regulations.gov> using Docket No. FDA-2010-N-0477.

- The **Federal Register** notice that requested notification of stakeholder intention to participate in consultation meetings is available at <http://edocket.access.gpo.gov/2010/pdf/2010-30713.pdf>.

- Additional information regarding implementation of the BPCI Act is available at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/UCM215031>.

Dated: May 4, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, e-mail [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Reports Clearance Office on (301) 443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

#### Proposed Project: Title (OMB No. 0915-NEW)—[NEW]

Authorized through the Patient Navigator Outreach and Chronic Disease Prevention Act of 2005 (Pub. L. 109-18), as amended by the Patient Protection and Affordable Care Act (Pub. L. 111-148), the Patient Navigator Outreach and Chronic Disease Prevention Demonstration Program (PNDP) supports the development and operation of projects to provide patient navigator services to improve health outcomes for individuals, including individuals with cancer and other chronic diseases, and health disparities populations. Award