

**FDA Public Meeting on Biosimilars (User Fees):
Implications for the Forthcoming Biosimilars
Regulatory Pathway¹**

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On December 16, 2011, the FDA held a public meeting on “Proposed Recommendations for a User Fee Program for Biosimilar and Interchangeable Biological Product Applications for Fiscal Years 2013 Through 2017,” in accordance with a Notice published in the Federal Register.² The meeting and the proposals it considered are part of the effort required by the Biologics Price Competition and Innovation Act of 2009 (“the Biosimilars Act”), enacted in April 2010, for FDA creation of an abbreviated approval pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed reference biological product. The specific motivation for the meeting and the FDA’s user fee proposals is the impending expiration of existing FDA statutory authority, conferred by the Federal Food, Drug, and Cosmetic Act’s prescription drug user fee provisions, in September 2012. New legislation to renew so-called PDUFA (Prescription Drug User Fee Act) authority will be required before September 2012, to continue the FDA’s authority to assess user fees to add to revenues needed to fund essential FDA review activities. As described in the FDA’s recent public meeting notice, the Biosimilars Act “directs FDA to develop recommendations for a biosimilars user fee program for FYs 2013 through 2017,” and to “consult with a range of groups,” in developing and revising recommendations, including the public at-large, “scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups (public stakeholders), and regulated industry stakeholders.”³ The Act requires the FDA “to revise [its proposed] recommendations” in light of such public and stakeholder meetings and “transmit them to Congress by January 15, 2012.”

The Forthcoming Biosimilars Application Pathway Guidelines

More importantly, the user fee recommendations are part of a larger effort by the FDA to carry out the Biosimilars Act’s instruction that the FDA “may, after opportunity for public comment, issue [general or specific] guidance ... with respect to the licensure of a [biosimilar and interchangeable] product[s] ...”⁴ The FDA has been working on an “Approval Pathway for Biosimilar and Interchangeable Biological Products” since early 2010. In November 2010, the FDA held a well attended two-day public meeting “to obtain input on specific issues and challenges associated with the implementation of the [Biosimilars Act].”

Among other issues addressed at the November 2010 public meeting were: the “scientific and technical factors the agency should consider in determining whether the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components;” the “appropriate analytical, animal, and clinical study or studies to assess the nature and impact of actual or potential structural differences between

the proposed biosimilar product and the reference product;" the extent to which "animal or clinical data comparing a proposed biosimilar product with a non-U.S.-licensed comparator product [may or should] be used to support a demonstration of biosimilarity to a U.S.-licensed reference product;" factors in developing a new pharmacovigilance program for such products; whether each new biosimilar product should be given a unique nonproprietary name, along with some distinguishing prefix or suffix; a safeguard "to assist the healthcare community when prescribing, administering, and dispensing biological products to prevent inadvertent substitution;" issues relating to the 12-year period of data exclusivity created by the Biosimilars Act for reference products, and other issues.⁵

All of these issues are likely to be addressed in a new FDA biosimilars pathway guidance. In public interviews in late September 2011, Janet Woodcock, Director of the FDA Center for Drug Evaluation and Research (CDER), stated that the FDA had "recently completed" its work on the new biosimilars pathway guidelines and that the FDA would release those regulatory guidelines for biosimilars by the end of 2011. Another FDA professional stated, in a different interview, that as of the end of September, release of the draft guidelines "could come 'as early as the next few weeks, maybe even days.'"⁶ At a two-day meeting in early December 2011, the FDA's Associate Director for Biosimilars, Leah Christl, stated that "the agency remains committed to issuing three general guidance documents on biosimilars by the end of December. The documents have left FDA and gone up to HHS (United States Department for Health and Human Services) for review."⁷

Commenting on the FDA's user fee proposal, Ms. Christl said that agreement among stakeholders and the FDA, resulting from consultation during the prior months and now set forth in the user fee proposal considered at the December 16 public meeting, "lays out some of our thoughts about interacting with sponsors and the need for IND (Investigational New Drug)," and that "[w]e really de-couple the need to have an IND from our ability to work with sponsors because we think it's very important to have a mechanism and a way to work [with them] even if they don't open an IND."

Some indications of the substance of the new biosimilar pathway guidelines have appeared in prior FDA releases about proposed user fees. In May 2011, the FDA published a Notice in the Federal Register, setting forth its then current user fee proposal, titled "Options for a User Fee Program for Biosimilar and Interchangeable Biological Product Applications for Fiscal Years 2013 Through 2017."⁸ In that earlier Notice, the FDA stated that it expects that:

- “marketing application review, preapproval facility inspections, and safety issues will be comparably complex ...,”
- “the complexity and level of effort required for FDA oversight of manufacturing and post-market safety issues for [biosimilars will] be comparable” to the effort for reference products, and
- the “same expert scientific teams that conduct FDA’s review of [BLAs] will typically be involved in the review of [biosimilar] applications.”⁹

In other public comments in May 2011, the FDA suggested that it is likely to take a “stepwise” approach, that rigorous analytical testing to show similarity will be required first, and that the FDA will then “determine on a case-by-case basis how much animal and clinical data are required.”¹⁰

In August 2011, several FDA officials published an article in the prestigious *New England Journal of Medicine* that may have provided further insight into the substance of what may become the new biosimilar pathway guidelines.¹¹ Confirming other public pronouncements, the article stated:

Fortunately, *progress in the characterization and understanding of biologics now permits demonstration that some products are highly similar to a reference product.* ... Given the complex nature of biologics, it’s unlikely that a “one size fits all” systematic assessment of biosimilarity can be developed. Instead, FDA scientists will need to integrate various types of information to provide an overall assessment that a biologic is biosimilar to an approved reference product.

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... Such a “totality of the evidence” approach can also be applied to assessing biosimilars, since it seems possible to exceed a current state-of-the-art analytic characterization by evaluating more attributes and combinations of attributes at greater sensitivities with multiple complementary methods. There may be strategies that allow a “fingerprint”-like identification of very similar patterns in two different products. Such strategies were used in supporting the approval of a generic low molecular- weight heparin product, enoxaparin — which, though it differs from proteins in important ways, is structurally complex. *Although additional animal and clinical studies will generally be needed for protein biosimilars for the foreseeable future, the scope and extent of such studies may be reduced further if more extensive fingerprint-like characterization is used.*

* * * * *

The FDA evaluation of biosimilarity must consider the product’s complexity, formulation, stability, and the usefulness of biochemical and functional characterizations, and incorporate these factors into a risk-based approach. The

mechanistic understanding of the clinical effect of a biologic, and the level of clinical information available about it, will also affect the evaluation of risk, and the manufacturing processes may introduce potential variants or impurities that could affect risk. Evaluating biosimilarity with a risk-based approach is scientifically appropriate and familiar to the FDA, whose decisions are commonly based on reducing residual uncertainty to an acceptable level in any given clinical setting.

Immunogenicity remains a critical factor when assessing biosimilarity, and the FDA will evaluate immunogenicity in a risk-based manner. For example, aggregation of proteins may be associated with higher risks of immunogenicity, and the risks related to an immune response are greater with products that stimulate immunity to non-redundant self-proteins, such as erythropoietin.

The FDA process for biosimilars must include *product-specific safety monitoring*. History suggests that pharmaceutical companies will make manufacturing-related changes to biologics periodically throughout their lifecycles, and *even small changes could affect safety or efficacy*. Tracking adverse events associated with the use of reference and biosimilar products will be difficult if the specific product or manufacturer cannot be readily identified, and appropriate strategies must be developed to ensure the implementation of robust, modern pharmacovigilance programs for biologics.¹²

Implications of the User Fee Notice and Hearing

The FDA's Notice of the December 16, 2011, public meeting did not repeat many of these earlier comments about the forthcoming biosimilars pathway guidelines. Nevertheless, that Notice provided some additional information about what may be subject matter in the pathway guidelines, in the description of the proposed uses of user fees set forth in the Notice:

Under the proposed biosimilars user fee program, FDA would be authorized to spend biosimilars user fees on Agency activities related to the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements. This would include activities related to biosimilar biological product development meetings and investigational new drug applications (INDs). It would also include development of the scientific, regulatory, and policy infrastructure necessary for review of biosimilar biological product applications, such as regulation and policy development related to the review of biosimilar biological product applications, and development of standards for products subject to review and evaluation.

It would cover FDA activities at the application stage, such as review of advertising and labeling prior to approval of a biosimilar biological product application or supplement; review of required post-marketing studies and post-marketing studies that have been agreed to by sponsors as a condition of approval; the issuance of action letters that communicate decisions on biosimilar biological product applications; and inspection of biosimilar biological product establishments and other facilities undertaken as part of FDA's review of pending biosimilar biological product applications and supplements (but not inspections unrelated to the review of biosimilar biological product applications and supplements). Finally, it would include

some activities at the post-approval stage, such as *postmarketing safety activities with respect to biologics approved under biosimilar biological product applications or supplements*.

The December public meeting Notice also describes the type and timing of meetings that the FDA expects to have in the course of reviewing a biosimilar application, and the extent to which the FDA will meet performance goals that reflect achievement of these timing standards. These performance goals appear to indicate that the FDA plans to be able to have a series of at least five separate meetings with a biosimilar applicant, relating to review of an application, planning for additional clinical and analytical tests, and reviewing the results of those tests. The Notice appears to indicate that, at least as a goal, those meetings would occur within about a one year period.¹³

Comments by Speakers at the December 16 Public Meeting of User Fees

A formal transcript of the December 16, 2011, public meeting will be prepared. One of our group members attended the hearing. In summary, FDA presented the user fee proposal in abbreviated form. Three public stakeholders made comments, as did three industry stakeholders – PhRMA (Pharmaceutical Research and Manufacturers of America), BIO, and GPhA (Generic Pharmaceutical Association). All agreed that the user fee proposal itself was acceptable and urged its adoption by Congress. These comments were simply a reflection that the present user fee proposal results from negotiations between the FDA and a wide variety of such stakeholders, that yielded an agreement. More interesting, however, were comments made by several speakers about issues that were *not* directly related to the specific contours of the proposed user fee program.

Dr. Shein-Chung Chow, a Duke University School of Medicine Professor in the Department of Biostatistics and Bioinformatics, spoke with slides¹⁴ about the number and kinds of clinical trials that should be considered in assessing whether a proposed product is “highly similar,” and thus a biosimilar product, within the meaning of the Biosimilars Act. He also spoke about the number and kinds of clinical trials that should be considered in assessing whether a product meets statutory definitions of interchangeability.¹⁵ Among other things, he described the differences between “non-inferiority” and “equivalency,” from a statistical standpoint. He appeared to suggest that, in assessing whether a product is a biosimilar, testing should, at minimum, assess the non-inferiority of a proposed biosimilar product, gauging non-inferiority against a range, or a particular biologic or other property, such as the product’s pharmacokinetics, exhibited by the reference product. He added that to

assess “equivalency,” it would also be necessary to assess whether the proposed biosimilar product is or is not *superior* to the reference product in such properties for characteristics, that is, “non-superiority.” The suggestion, if not direct comment of Dr. Chow, was that, from a statistical standpoint, “equivalency” can be found only if a product meets *both* non-inferiority and non-superiority assessments.¹⁶

However illogical the result may seem, because all manufacturers, including biosimilar sponsors, seek to make their products safer and more effective, the implication of these remarks, if adopted by the FDA, may well be that “biobetters” may *not* be considered as “biosimilars” and could, as a result, be considered to be outside the scope of the proposed biosimilars pathway. From both a public health and industry standpoint, this result would be highly undesirable and an impediment to real innovation by biosimilar developers.¹⁷

One of the industry stakeholder representatives who spoke on behalf of the Biotechnology Industry Organization (BIO), briefly discussed three topics that may have significance in future biosimilars pathway development, particularly as the public comment period on the forthcoming pathway guidelines is underway. Andrew Emmett, the speaker, first stated that there is a need to clearly and appropriately delineate the boundaries between those applications that will be considered under FDA’s long-standing BLA (Biologics License Applications) regulatory pathway and those which will be subject to the new biosimilars pathway. Second, he suggested, in a manner that seemed at odds with the anti-“patent linkage” position taken by the pharmaceutical and biologics industry prior to enactment of the Biosimilars Act, that the FDA should adopt a “simple certification procedure,” under the Biosimilar Act’s patent resolution and litigation procedures, through which parties, especially biosimilar sponsors, should be required to “certify” their compliance with those procedures.¹⁸ Third, he suggested that the FDA must provide “clear protection” for BLA confidential information, adding that there should, in some unspecified context, be reliance only on publicly disclosed BLA information.

Each of these three comments could have significant implications for the biosimilars pathway and approval process, whether the results they appear to enjoin occur as a result of FDA guidance or regulation, or through some effort, in the context of Congressional renewal of the FDA’s user fee authority. It was unclear at the public meeting whether BIO’s representative meant that any of these implications should be drawn or that they were intended, or whether there is any real change in BIO’s previously announced positions.

For example, an overly refined delineation of boundaries between BLA applications and those which will be subject to the new biosimilars pathway may well, once again, make development of “biobetters” less attractive. If every “biobetter,” including those which are simply “superior” biosimilars, must only be the subject of the BLA process, so that the FDA would not be permitted, as it is statutorily in the Biosimilars Act, to rely at least on “publicly-available information regarding the Secretary’s previous determination that the reference product is safe, pure, and potent,”¹⁹ or other information previously submitted to and known by “same expert scientific teams” that conducted the FDA’s review of the reference product BLAs, then approval of *every* “biobetter” may be subject to full and expensive human clinical testing. Once again, from both a public health and industry standpoint, this result would be highly undesirable and an impediment to real innovation by biosimilar developers. Combined with the implications of Dr. Chow’s remarks about “equivalency,” such a “clear delineation,” at odds with the flexibility otherwise championed by all parties and seemingly embodied in the Biologics Act itself, may be a means by which reference product sponsors could effectively preclude *any* “biobetters” from competitive entry in the marketplace, even if the therapeutic benefits of such “biobetters” were obvious.

A public speaker, general counsel of Momenta Pharmaceuticals, Bruce Leicher, strongly counseled against any new FDA involvement in the patent resolution process explicitly set forth in the Biosimilars Act, a process now completely outside *any* FDA involvement. There is no “Orange Book” for biologic products, for example, as much as that may have been beneficial to the biosimilars patent resolution and litigation process. He suggested or implied that *no* change in that procedure should be considered, even a “simple certification process,” whether through guidance, regulation or legislation, without disrupting the balance struck in the Biosimilars Act.

Conclusion

These comments portend a robust and potentially contentious discussion, if not dispute, in the forthcoming months, over a number of issues that may well be addressed in the forthcoming FDA biosimilars pathway guidance. Given the need for legislative action to renew the FDA’s authority to establish and collect user fees, including the new biosimilars user fees that were the subject of the December 16 public meeting, the comments made by stakeholders and public speakers at the meeting may predict a legislative battle, as well, even over issues unrelated to the apparently agreed on under fee program. In any event, they reflect that the process of establishing a framework for charging and collecting user

fees for FDA review of biosimilar applications, including the public meeting on December 16, 2011, may well have implications for the forthcoming FDA guidance on the substance of a new biosimilars application pathway. Time will tell.

¹ This client alert has been prepared by members of Schiff Hardin's Intellectual Property Practice, who concentrate their practices in biologics and pharmaceutical products, including D. Christopher Ohly (Washington, D.C.), Sailesh K. Patel (Chicago), George Yu (San Francisco) and Steven Hankins. For further information about the contents and specific subject matter of this client alert, please contact Chris Ohly, in our Washington, D.C. office.

² The Notice set forth specific questions related to a biosimilars user fee program that were considered at the public meeting, along with others:

- If the existing fee structure under the Prescription Drug User Fee Act (PDUFA) were to be considered as a model in establishing a user fee structure for applications and supplements for proposed biosimilar and interchangeable biological products, what factors and changes should FDA take into consideration, and why?

- What factors should FDA take into account when considering whether to recommend that user fees for biosimilar and interchangeable biological products should also be used to monitor safety after approval?

³ See Biosimilars Act §7002(f).

⁴ See Biosimilars Act §7002(a)(2), adding 42 U.S.C. § 262(k)(8).

⁵ The Biosimilars Act create data exclusivity for reference products, specifically providing that "[a]pproval of an application under this subsection may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed." See Biosimilars Act §7002(a)(2), adding 42 U.S.C. § 262(k)(7).

⁶ See "FDA Biosimilar Guidelines Complete, Awaiting Publication," http://www.sun-sentinel.com/health/sns-rt-us-biosimilarstre78m6ql-20110923_0_1332636.story, quoting an article in *Biocentury*, <http://www.biocentury.com/dailynews/politics/2011-09-22/fda-moving-forward-on-biosimilars>; and "FDA Biosimilar Guidance May Be Here In 'Days'," <http://www.pharmalot.com/2011/09/fda-biosimilar-guidance-may-be-here-in-days/>.

⁷ See "Biosimilar User Fee Agreement Allows For Reliance On Foreign Clinical Data, FDAer Says," *Pink Sheets Daily*, December 14, 2011, <http://www.elsevierbi.com/Publications/The-Pink-Sheet-Daily/2011/12/14/Biosimilar-User-Fee-Agreement-Allows-For-Reliance-On-Foreign-Clinical-Data-FDAer-Says?result=3&total=7&searchquery=%253fq%253dBiosimilar%2520User%252520Fee%252520Agreement%252520Allows%252520For%252520Reliance%252520On%252520Foreign%252520Clinical%252520Data%25252c%252520FDAer%252520Says>.

At the same meeting, Ms. Christl is reported to have said that the "agency had received 31 pre-IND meeting requests for biosimilars that reference 11 products," and that the FDA has "held 21 pre-IND meetings with sponsors, and seven INDs for biosimilar development programs had been opened." *Id.* She is reported to have added that "that not every development program is going to have an IND," and that it "depends on the program that the sponsor has and whether or not they'll be conducting trials in the U.S. or not." She commented that she did not "want folks to think there's only seven programs that are going on," adding that "They may not have an IND. They may just continue under a pre-IND stage where we'll interact with the sponsor." *Id.*

Ms. Christl is reported to have said that the FDA "has been very open about allowing sponsors to rely on data from foreign trials that do not use a U.S.-licensed reference product," and that [s]ponsors may be able provide adequate data and information to demonstrate similarity between a U.S.-licensed reference product and a non-U.S. reference product [with "adequate bridging data and justification", thereby allowing them to leverage information from foreign studies." *Id.* "Baseline requirements under this scenario," she added, "likely would include a three-way analytical comparison and a three-way pharmacokinetic/pharmacodynamic comparison to demonstrate sufficient similarity between the ex-U.S. reference product, the U.S.-licensed reference product and the biosimilar." *Id.*

⁸ See <http://www.federalregister.gov/articles/2011/12/07/2011-31499/biologics-price-competition-and-innovation-act-of-2009-proposed-recommendations-for-a-user-fee>.

⁹ These comments suggest that the FDA may rely on data submitted by a reference product sponsor in reviewing an application for a biologics product, whether made through a Biologics License Application (BLA) or an application made under the new Biosimilars Act. Such information will be in the mind and memory of “the “same expert scientific teams that conduct FDA’s review of [the reference product BLAs] ...”

¹⁰ In an interview in May 2011, Rachel Behrman, the FDA’s Associate Director for Medical Policy in the Center for Drug Evaluation and Research said that the FDA will review biosimilars in a two-step process. That process will be detailed in a series of *agency guidance documents*, the first of which *will be published at least by year’s end*. She added:

“Starting with an assumption that approved biologics are already safe and effective ... the agency will be looking for data establishing that biosimilars submitted for approval have the same effect in patients without illustrating clinically meaningful differences.”

“Companies first will submit analytic data showing how similar their compounds are to an FDA-approved innovator version. The agency then will determine on a case-by-case basis how much animal and clinical data are required for approval ... Duplicative testing is unethical ... What I think we’ve shown in our decision on generic enoxaparin, is we may be able to take the European experience ... and go one step further.”

See http://www.burrillreport.com/article-fda_to_issue_guidance_on_biosimilars_by_year_end_.html; and <http://www.biocenturytv.com/fullplayer.aspx#/BC+Show+33%3A+Biosimilars%3A+Will+the+U.S.+Plan+Work%3F/BioCentury+05.01.11+%2D+%5B1%5D+The+Pathway/608459720001/923169085001/924495749001>

¹¹ See Steven Kozlowski, M.D., Janet Woodcock, M.D., Karen Midthun, M.D., and Rachel Behrman Sherman, M.D., M.P.H., “Developing the Nation’s Biosimilars Program, *New England Journal of Medicine*, 365:385-388 (August 4, 2011).

¹² *Id.* (emphasis added).

¹³ At the same time, however, the FDA set forth its goal to have such meetings, within that time frame, only 70% of the time in the first year (FY 2013), increasing to 90% in the final years (FY 2017). Of course, the FDA’s ability to achieve these goals will be affected, among other things, by the number and complexity of biosimilar applications that may be initiated and the number of different biologic products that may be the subject of those applications.

None of the meetings, as described in the Notice, would affect the timing of biosimilar manufacturing facilities inspections, which are also required by the Biosimilars Act, and which may also be part of the subject matter of the forthcoming FDA pathway guidelines.

¹⁴ The slides and the others exhibited at the public meeting will soon be published in the FDA’s Docket concerning biosimilars user fees. <http://www.regulations.gov/#!docketDetail;dct=FR%252BPR%252BN%252BO%252BSR;rpp=10;po=0;D=FDA-2011-N-0326>. Another docket contains information about the FDA’s biosimilar pathway considerations. <http://www.regulations.gov/#!docketDetail;dct=FR%252BPR%252BN%252BO%252BSR;rpp=10;po=0;D=FDA-2010-N-0477>.

¹⁵ The Biosimilars Act defines the “term ‘interchangeable’ or ‘interchangeability’, in reference to a biological product that is shown [be a “biosimilar”],” as a term that “means that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.” See Biosimilars Act §7002(b)(3), amending 42 U.S.C. § 262(i).

¹⁶ For lengthier explanations of the foundations of Dr. Chow’s remarks, see S. C. Chow *et al.*, *Scientific Factors For Assessing Biosimilarity and Drug Interchangeability of Follow-On Biologics*, Biosimilars 2011:1 13-26 (2011), www.dovepress.com/getfile.php?fileID=10321 and S. C. Chow, *Quantitative Evaluation of Bioequivalence/Biosimilarity*, *J. Bioequivalence and Bioavailability* S1 (2011), www.omicsonline.org/0975-0851/JBB-S1-002.pdf and <http://www.omicsonline.org/0975-0851/JBB-S1-002.php>.

¹⁷ Dr. Chow also remarked about the types and statistical significance of alternating and switching tests for interchangeability. While those remarks had their own scientific and regulatory implications, they are not further discussed here.

The Biosimilars act creates an incentive for development of interchangeable products, in the form of marketing exclusivity for the first biosimilar product that receives a determination of interchangeability for any condition of use. See Biosimilars Act §7002(a)(2), adding 42 U.S.C. § 262(k)(6). Under the statute, the FDA may not, after approving such a first interchangeable product, make a determination that a second or subsequent biological product is interchangeable for any condition of ; use until the earlier of (1) 1 year after the first commercial marketing of the first interchangeable biosimilar biological product; (2) 42 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has been sued; (3) 18 months after certain other litigation events, or (4) 18 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has not been sued.” *Id.*

¹⁸ See, e.g., Robert Armitage, “ From Hatch-Waxman to the Biologics Price Competition and Innovation Act: A Roadmap for Assuring Access to the Best New Medicines”, AIPLA Spring 2010 Meeting Paper, at 5, 9-11, 16 (April 2010) http://www.aipla.org/committees/committee_pages/Biotechnology/Committee%20Documents/Committee%20Presentations/2010.Spring/Armitage.pdf

¹⁹ See Biosimilars Act §7002(a)(2), adding 42 U.S.C. § 262(k)(2)(a)(2)(iii). See also, *id.*, adding 42 U.S.C. § 262(k)(2)(a)(2)(ii) (“The Secretary ... may determine, in the Secretary’s discretion, that [statutorily described element of a biosimilar application] is unnecessary.”); and *id.*, adding 42 U.S.C. § 262(k)(3)(...the Secretary *shall* license the biological product under this subsection if .. the Secretary determines that the information submitted in the application ... is sufficient to show that the biological product ... is biosimilar to the reference product ...”).

FDA Description of User Fee Proposal

To learn more about the presentation by the FDA, [please click here](#)
To view the agenda including speakers bio's, [please click here](#)

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