Association for Accessible Medicines

Your Generics & Biosimilars Industry

February 11, 2019

Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2015-D-4750; AAM Comments on FDA's Draft Questions and Answers and Final Guidance Regarding the Agency's Interpretation of the "Deemed to be a License" Provision of the Biologics Price Competition and Innovation Act of 2009

The Association for Accessible Medicines and the Biosimilars Council (collectively referred to as "AAM") are pleased to provide comments to the Food and Drug Administration ("FDA" or "the Agency") on its draft and final guidances for industry on implementation of the "Deemed to be a License" provision of the Biologics Price Competition and Innovation Act of 2009 ("BPCIA").[1] AAM is submitting consolidated comments that address both FDA's draft guidance entitled *The "Deemed to be a License" Provision of the BPCI Act: Questions and Answers* ("Draft Q&A Guidance") and FDA's final guidance on *Interpretation of the "Deemed to be a License" Provision of the Biologics Price Competition and Innovation Act of 2009* ("Final Guidance").

AAM represents the manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. Generics represent greater than 90% of all prescriptions dispensed in the U.S. by volume, but only 23% of the cost expended on prescription drugs. AAM is the sole association representing America's generic pharmaceutical sector in the United States. The Council, a division of AAM, works to ensure a positive regulatory, reimbursement, political and policy environment for biosimilar products, and educates the public and patients about the safety and effectiveness of biosimilars. Areas of biosimilar focus include education, access, the nascent regulatory environment, reimbursement and legal issues. Member organizations include companies and stakeholder organizations working to develop biosimilar products with the intent to participate in the U.S. market.

[1] *See* 83 Fed. Reg. 63894-98 (Dec. 12, 2018) (Docket No. FDA-2015-D-4750).

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Although AAM agrees with many aspects of the guidance documents, AAM is concerned that FDA's announced policy with respect to pending applications under Section 505 of the Federal Food, Drug, and Cosmetic Act ("FFDCA") that are not approved by March 23, 2020 is contrary to the express language of the BPCIA and will unnecessarily complicate and delay the approval of lower-cost versions of biological medicines that currently are regulated under the FFDCA ("transitional biologics"). AAM also disagrees with FDA's newly-announced "one-size-fits-all" approach to transitioning approved NDAs, including approved 505(b)(2) applications, to approved 351(a) applications (rather than 351(k) applications).

Because FDA's proposed, and final policies will impair patient access to affordable alternatives to important brand name biologics, including insulins, contrary to the language of the BPCIA and Congressional intent, AAM respectfully requests that FDA amend its policy to facilitate a streamlined and flexible transition for both approved and pending applications.

I. FDA Should Amend Its Policies Regarding Pending NDAs

In its Final Guidance, FDA states that "[a]fter March 23, 2020, the Agency will not approve any application submitted under section 505 of the FD&C Act for a biological product subject to the transition provisions that is pending or tentatively approved."[2] In order to obtain approval, such applications (even those with tentative approval) must be withdrawn and resubmitted under section 351(a) or 351(k) of the Public Health Service Act ("PHS Act").

A. FDA's Blanket Non-Approval Policy Conflicts with the Relevant Statutes, Is Arbitrary and Capricious and Will Significantly Impair Ongoing Development Programs

AAM strongly opposes FDA's blanket "non-approval" policy for NDAs and 505(b)(2) that are tentatively approved or otherwise pending as of March 23, 2020. As AAM previously explained,[3] the policy is already having a devastating effect on current development programs for many important protein products, including insulins, thereby impairing competition from lower-cost biological medicines, increasing healthcare costs in the United States, and, most importantly, limiting patient access to affordable biological products. AAM believes these results are antithetical to the overriding goals of the BPCIA, which were to *increase* competition and access and *lower* healthcare costs in the United States.

FDA's interpretation is disrupting ongoing development plans and delay the approval of affordable transitional biological products in at least two ways. First, it has created a regulatory "dead zone" during which prospective sponsors cannot submit ***any*** applications for approval of follow-on versions of transitional biological products under either the FD&C Act or the PHS Act. This is because reasonable sponsors will refrain from submitting NDAs, including 505(b)(2) applications, at some point well before March 23, 2020 because of the meaningful risk that such

[2] Final Guidance, at 5.

[3] In prior comments, AAM objected to this proposal because it is inconsistent with the relevant statutes and creates a "regulatory dead zone" that will severely impair the development of competing versions of important transitional biologics like insulin. Comments from GPhA and Biosimilars Counsel, Docket No. FDA-2015-D-4750-0010 (May 13, 2016). AAM incorporates its prior comments and objections herein by reference.

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applications will not be approved prior to that date and thus will need to be withdrawn and re-submitted. At the same time, FDA's policy blocks sponsors from submitting 351(k) applications for biosimilar or interchangeable biological products until after March 23, 2020 because of the absence of any "reference product" prior to that date. As a result, development, review and approval activities for transitional biological products will come to a standstill for several years.

Second, for section 505 applications that are submitted prior to March 23, 2020 but not approved by then, FDA's policy requires such applications to be "withdrawn and resubmitted under section 351(a) or 351(k) of the PHS Act, as appropriate."[4] This will cause unnecessary disruptions to the review process and impose extended user fee goal dates up to an additional 12 months on such "resubmitted" applications. FDA's "withdrawal and resubmission" policy applies even to applications that have been tentatively approved by the Agency prior to March 23, 2020, and for which all scientific review activities have been completed.

This is not how Congress intended the BPCIA or its transition provisions to function. On the contrary, FDA's interpretation conflicts with the clear statutory language of both the BPCIA and the FD&C Act and thus must be modified.

First, FDA's interpretation conflicts with the FFDCA and its implementing regulations. The FFDCA and FDA regulations carefully set forth the available grounds for refusing to approve an NDA, including a 505(b)(2) application.[5] Significantly, none of those grounds would apply to an NDA for a transitional biological product that is still pending after March 23, 2020, and FDA does not identify any statutory or regulatory basis in the BPCIA or elsewhere giving it authority to refuse to approve pending full NDAs or 505(b)(2) applications after March 23, 2020. This is because no so such authority exists. Accordingly, FDA's blanket non-approval policy conflicts with the BPCIA, the FFDCA, and applicable FDA regulations.[6]

Second, FDA's interpretation ignores and makes inoperative the BPCIA transition provision that expressly permits sponsors to submit applications under section 505 up until March 23, 2020.[7] FDA's blanket policy not to approve such applications after that date voids this provision by effectively prohibiting sponsors from submitting section 505 applications months or even years prior to March 23, 2020. FDA's interpretation thus makes the March 23, 2020, date established by Congress inoperative. It is well-established, however, that an interpretation of a statute that renders any provision inoperative must be rejected.[8]

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[4] Final Guidance, at 6.

[5] 21 U.S.C. § 355(d); 21 C.F.R. § 314.125.

[6] In its 2016 draft version of the Final Guidance, FDA argued that it could refuse to approve 505(b)(2) applications and ANDAs after March 23, 2020, because, at that time, the relevant "listed drugs" will be removed from the Orange Book. But FDA is not authorized to remove an approved product from the Orange Book unless its approval is suspended or withdrawn, or it is voluntarily withdrawn from sale, for reasons of safety or effectiveness.21 U.S.C. § 355(j)(7). Moreover, the suspension or withdrawal of an approved NDA is grounds for denying approval of an ANDA that relies upon it *only if* the suspension or withdrawal is based upon safety or effectiveness reasons. 21 U.S.C. § 355(j)(4)(D)(I); 21 C.F.R. § 314.127(a)(9), (10), (11). In this case, of course, FDA's withdrawal of the relevant NDAs has nothing to do with safety or effectiveness and thus does not provide any justification for FDA to deny approval of pending 505(b)(2) applications or ANDAs for transitional biological products after March 23, 2020.

[7] *See* BPCIA, § 7002(e)(2).

[8] *See Milner v. Dept. of Navy*, 131 S. Ct. 1259, 1268 (2011); *TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001) (noting canon of statutory interpretation that statutes should be read to avoid making any provision "superfluous, void, or

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Finally, FDA's interpretation would lead to absurd results. It necessarily assumes that Congress specifically authorized the submission of applications that it knew could never be approved and that, in fact, had to be withdrawn and re-submitted shortly after initial submission. This, of course, is absurd. Congress authorized the submission of section 505 applications until March 23, 2020, because it expected FDA to review and approve those applications after March 23, 2020, regardless of how close they were submitted to the cut-off date. There is nothing in the BPCIA transition provision that even suggests FDA can or should refuse to approve a pending NDA after March 23, 2020.[9] Because it is well-established that "courts will not construe a statute in a manner that leads to absurd or futile results,"[10] FDA's interpretation of the BPCIA transition provisions is impermissible.

AAM also believes FDA's interpretation of the BPCIA transitional provisions is arbitrary and capricious in violation of the APA because it deviates from established precedent without adequate justification or explanation. In past cases where FDA has moved products from one regulatory category to another, the agency has adopted a policy of "ensur[ing] that the transition from one jurisdictional category to another would take place with minimal disruption to the marketplace and minimal prejudice to the firms subject to the move."[11] In this case, by contrast, FDA has adopted a policy that it admits will have a "significant impact on development programs" for transitional biological products. Indeed, it is difficult to imagine an interpretation of the BPCIA transition provisions that would be *more disruptive* to the marketplace or *more prejudicial* to sponsors subject to the transition. It is a basic principle of administrative law that "agency action cannot stand when it is 'so inconsistent with its precedents as to constitute arbitrary treatment amounting to an abuse of discretion."[12] FDA's failure to follow past precedent by ensuring that the BPCIA transition takes place with "minimal disruption" to the marketplace and "minimal prejudice" to affected sponsors, therefore, is arbitrary and capricious in violation of the APA.

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insignificant" (internal quotation marks omitted)); *Edison Elec. Inst. v. EPA*, 996 F.2d 326, 335 (D.C. Cir. 1993) (applying "the elementary canon of construction that a statute should be interpreted so as not to render one part inoperative") (citation omitted); *FTC v. Manager, Retail Credit Co.*, 515 F.2d 988, 994 (D.C. Cir. 1975) ("The presumption against interpreting a statute in a way which renders it ineffective is hornbook law.").

[9] The fact that the BPCIA transition provision only applies to approved NDAs does not provide any support for FDA's position either. Even if FDA does not have explicit authority to transition NDAs approved after March 23, 2020, it does not have explicit authority to refuse to approve pending NDAs after that date either. And as discussed below, Congress was well aware that FDA retains plenary authority to transition products between appropriate classes even in the absence of explicit Congressional authorization, which authority FDA has used on numerous occasions.

[10] *Nixon v. Missouri Municipal League*, 541 U.S. 124, 138 (2004) (citing *United States v. American Trucking Assns., Inc.*, 310 U.S. 534, 543 (1940); *SEC v. DiBella*, 587 F.3d 553, 572 (2d Cir. 2009) ("Where an examination of the statute as a whole demonstrates that a party's interpretation would lead to absurd or futile results plainly at variance with the policy of the legislation as a whole, that interpretation should be rejected.") (quoting *Yerdon v. Henry*, 91 F.3d 370, 376 (2d Cir. 1996)).

[11] *See* FDA Consolidated Response to Pending Citizen Petitions on the Regulation of Ultrasound Contrast Agents, Docket No. 96P-0511, p. 59 (July 25, 1997) ("Consolidated Response").

[12] *Garrett v. FCC*, 513 F.2d 1056, 1060 (D.C. Cir. 1975) (quoting *Herbert Harvey Inc. v. NLRB*, 424 F.2d 770, 780 (D.C. Cir. 1969)); *Greater Boston Television Corp. v. FCC*, 444 F.2d 841, 852 (D.C. Cir. 1970) (citations omitted), *cert. denied*, 403 U.S. 923 (1971) ("an agency changing its course must supply a reasoned analysis indicating that prior policies and standards are being deliberately changed, not casually ignored, and if an agency glosses over or swerves from prior precedents without discussion it may cross the line from tolerably terse to the intolerably mute.").

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B. FDA's Policy Unfairly Imposes Duplicative User Fees on Applications for Biosimilar and Interchangeable Biological Products

According to FDA's Draft Q&A Guidance, an applicant who withdraws a pending NDA or 505(b)(2) application and submits a full BLA application for the same product will not be required to pay a new application fee if certain criteria are met.[13] However, if the applicant submits a 351(k) application for the same product, the applicant would be assessed a biosimilar biological product application fee in addition to the PDUFA fee previously submitted for the original application.[14] For fiscal year 2019, application fees under BsUFA are approximately $1.75 million.

AAM objects to this policy because it is imposes unfair and duplicative user fee obligations on applicants seeking to develop biosimilar and interchangeable versions of transitional protein products prior to March 23, 2020. As such, FDA's proposed policy regarding user fees, coupled with its final "non-approval" policy described above, will create additional, substantial disincentives for applicants to develop and seek approval of these products prior to March 23, 2020, further exacerbating the "regulatory dead zone." AAM believes this runs directly counter to the intent of Congress in enacting the BPCIA transition provisions.

C. FDA Should Administratively Convert Pending NDAs and 505(b)(2) Applications to Pending BLAs After March 23, 2020

For all these reasons, AAM respectfully requests that FDA modify its policy regarding pending applications in a way that (a) is consistent with the statutory language and underlying goals of the BPCIA, and (b) minimizes disruptions to the development, review and approval of, and patient access to, affordable transitional biological products. In particular, AAM respectfully requests FDA to adopt a new policy that complies with the following principles:

1. Pending applications submitted under section 505 for a protein product subject to the transition provisions will, on March 23, 2020, be deemed to be pending applications submitted under section 351(a) or 351(k) of the PHS Act, as appropriate;

2. FDA will review the re-designated applications based upon the data and information already submitted and will rely and build upon the review already completed by the applicable review division;

3. In order to meet any new or different statutory requirements for biologics regulated under the PHS Act, applicants will be permitted to amend their pending 351(a) or 351(k) application after the re-designation;

4. For purposes of establishing a goal date under the Biosimilar User Fee Act ("BsUFA") or PDUFA, as applicable, the submission and filing dates of the 351(a)

[13] Draft Q&A Guidance, at 9.
[14] Draft Q&A Guidance, at 10.

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or 351(k) application will be based upon the submission and filing dates of the original section 505 application; and

5. Any application fees paid with the original application under section 505 will be credited toward the application fee required for a 351(a) or 351(k) application.

AAM believes FDA has ample authority to administratively convert pending NDAs and 505(b)(2) applications to pending BLAs, as described above. In its Final Guidance, FDA states that it will administratively convert any pending supplement to an approved NDA to a pending supplement to an approved BLA.[15] The logic here is that the approved 505(b)(2) biologic drug will be converted to a 351(1) biologic drug, serving as the reference for the license supplement application. In a similar manner, the RP for a 505(b)(2) application will remain an approved product, but one that is now considered to be a 351(a) biologic. Accordingly, the RP used in the studies incorporated into the 505(b)2) application is still suitable for use as the comparator product. And from a regulatory perspective, if FDA has authority to administratively convert pending NDA supplements to pending BLA supplements, it certainly has the authority to administratively convert pending NDAs (including 505(b)(2) applications) to pending BLAs. Indeed, FDA took this exact action in 1997 when it converted pending antibiotic applications to pending NDAs after repeal of section 507 of the FFDCA. Significantly, FDA took this action on its own initiative without specific authorization from Congress since the statutory transition provision at issue there, like here, addressed only "approved" applications, not pending applications.[16]

II. FDA Should Amend Its Proposed Policy Regarding Transition of Approved NDAs to Adopt a Case-by-Case Approach

In its Draft Q&A Guidance, FDA states that it interprets the relevant statutory provisions of the BPCIA and FFDCA "to mean that an approved NDA, including [a 505(b)(2) application], will be deemed to be a 351(a) BLA on the transition date."[17] This reflects a significant shift in the Agency's original position that an approved NDA, including a 505(b)(2) application, could be deemed to be either a full BLA under section 351(a) of the PHS Act or a biosimilar or interchangeable BLA under section 351(k) of the PHS Act, as appropriate.[18] While the Agency had not yet specified the factors that would apply to determine whether an approved NDA should be regarded as an approved 351(a) or 351(k) BLA,[19] the Agency's position that an approved NDA could be either an approved 351(a) or 351(k) was not in question.

AAM objects to FDA's proposed "one-size-fits-all" approach, which fails to recognize the wide diversity of products that are approved via the 505(b)(2) pathway. While some 505(b)(2) products may fit more comfortably in the 351(a) category, others are more akin to biosimilars and interchangeable biological products approved via section 351(k) of the BPCIA. Accordingly,

[15] Final Guidance, at 8.
[16] Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 125(d) (1997).
[17] Draft Q&A Guidance, at 7.
[18] Draft FDA Guidance, *Implementation of the "Deemed to be a License" Provision of the Biologics Price Competition and Innovation Act of 2009*, p. 5 (March 2016) ("Draft Guidance").
[19] Draft Guidance, at 5 n. 7.

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AAM requests that FDA adopt a case-by-case approach to determining whether a 505(b)(2) biological product is deemed to be a 351(a) or 351(k) biologic, taking into account, among other things, the biosimilarity criteria (*e.g.*, same dosage form, strength, route of administration), scope of reliance on a reference product, labeling, therapeutic equivalence rating, and the wishes of the product sponsor. AAM believes that this approach better reflects not only the wide breadth of products approved via the 505(b)(2) pathway but also the intent of Congress to provide access to affordable alternatives to brand name biologics in the form of biosimilar and interchangeable biological products.[20]

FDA's justification for adopting this new policy is not persuasive. FDA explains that its decision is based upon three considerations: (1) 505(b)(2) applications and full BLAs are both required to contain "full reports" of investigations establishing safety and effectiveness; (2) 505(b)(2) applications may differ from the reference product in certain respects (e.g., dosage form, route of administration); and (3) FDA reviews 505(b)(2) applications under a different statutory standard than a determination of biosimilarity or interchangeability.[21] While these reasons may justify treating some 505(b)(2) applications as full BLAs, they do not justify a blanket policy applying to all 505(b)(2) applications.

First, the 505(b)(2) pathway applies to a wide variety of products, from applications based on full clinical investigations of safety and effectiveness conducted by the sponsor to applications that rely almost entirely on FDA's previous findings of safety and effectiveness for a listed drug.[22] Thus, FDA's contention that all 505(b)(2) applications contain "full reports" similar to the "full reports" required of full BLAs ignores the reality of how FDA interprets and has applied the 505(b)(2) approval pathway historically.

Second, while some 505(b)(2) applications may entail differences from the reference product that would not be permitted in a 351(k) application (e.g., different dosage form), many other 505(b)(2) applications do not include such differences. FDA thus should adopt a case-by-case approach that looks at each product individually.

Finally, FDA's contention that it reviews 505(b)(2) applications under a different statutory standard than a determination of biosimilarity is inaccurate and exaggerates the differences between the statutory standards when applied to protein products. While the 505(b)(2) standards for approval are not exactly the same as the biosimilarity requirements, FDA has approved several protein products under section 505(b)(2) based upon a determination that the active ingredient in

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[20] AAM previously submitted comments to FDA setting forth its position regarding this issue, which are incorporated herein by reference. *See* AAM Response to December 4, 2017 Comments from Eli Lilly and Company, FDA-2015-D-4750-0018 (May 31, 2018).

[21] Draft Q&A Guidance, at 8.

[22] Some products are considered 505(b)(2) applications because, despite conducting full clinical investigations of safety and effectiveness, the applicant relied on a small amount of data, such as an animal study, to which it did not have a right of reference. Moreover, many 505(b)(2) applications rely almost entirely on FDA's prior findings of safety and effectiveness for a listed product. For example, hyaluronidase products, which are identified in the Draft Transition Guidance as examples of biological products regulated as drugs, relied almost entirely on FDA's previous findings of safety and effectiveness in a DESI evaluation for use published in 1970. These products, such as Amphadase (NDA #021665), Vitrase (NDA #021640), and Hylenex Recombinant (NDA #021859), were required only to conduct small clinical trials to evaluate allergenicity or hypersensitivity.

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the proposed product was "highly similar" to the reference product. FDA should accept such findings made in the 505(b)(2) context as meeting the biosimilarity requirements.

In summary, FDA should avoid a "one-size-fits-all" approach to transitioning 505(b)(2) biological products to biologic-licensed products.[23] Instead, a better approach is to treat 505(b)(2) biological products on a case-by-case basis, acknowledging that 505(b)(2) products are remarkably varied and that some sponsors intend their products to be marketed and treated as biosimilars.

III. AAM Agrees That "Deemed" BLAs Should Not Qualify for Reference Product Exclusivity

In its Final Guidance, FDA finalized its positions that "deemed" BLAs would not be eligible for (1) any unexpired period of exclusivity attaching to the corresponding NDAs, except orphan drug and pediatric exclusivity; or (2) any reference product exclusivity under the BPCIA.[24] AAM agrees with both of these positions. As FDA notes, after the transition date, any unexpired period of exclusivity or listed patent associated with an approved NDA would no longer be relevant to a "deemed" BLA or to a 351(k) application seeking to rely upon the deemed BLA as a reference product.

Moreover, AAM agrees that a "deemed" BLA is not entitled to the 4- or 12-year exclusivity periods available to biological products that are "first licensed" under section 351(a) of the PHS Act because such products are not "first licensed" under the PHS Act; instead, they are "deemed" to be licensed by operation of section 7002(e)(4) of the BPCIA. Awarding new 4- and 12-year exclusivity periods to such products would result in a massive, undeserved windfall to many previously-approved biological products that have been marketed for years and already have benefitted from the Hatch-Waxman exclusivity and patent listing protections, including the 30-month stay provision. There is no evidence that Congress intended to bestow a huge economic windfall on such biological products based on nothing more than an administrative "housekeeping" procedure designed to promote uniformity in regulatory requirements. Doing so, in fact, would run counter to one of the main purposes of the BPCIA: facilitating patient access to affordable alternatives to these important brand name biologics. FDA's decision to deny exclusivity to such products is thus sound on both public policy and legal grounds.

IV. AAM Agrees with FDA's Compliance Policy Regarding Labeling Requirements

Finally, AAM agrees with FDA's decision not to enforce certain labeling requirements for biological products regulated under section 351 of the PHS Act until March 23, 2025. As FDA notes, enforcing such requirements immediately on the transition date could disrupt the distribution of transitional biologics and impose unnecessary burdens on application holders.

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[23] The agency already recognized that this determination was not simple, and instead of announcing a policy in its Draft Transition Guidance, stated that FDA "intends to provide additional guidance regarding its approach for determining whether an approved application for a biological product under section 505 of the FD&C Act will be deemed a license for a biological product under section 351(a) or 351(k) of the PHS Act." Draft Transition Guidance at fn 7.

[24] Final Guidance, at 8-9.

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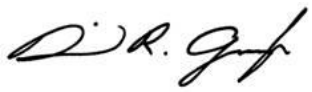
AAM believes that a five-year transition period is reasonable and consistent with past Agency practice.

V. Conclusion

For the reasons set forth above, AAM requests FDA to amend its "non-approval" policy regarding pending NDAs and 505(b)(2) applications announced in the Final Guidance and Draft Q&A Guidance, which creates a regulatory "dead zone" and would have a "significant impact" on ongoing development programs and the public health. In addition, FDA should not adopt a "one-size-fits-all" approach to determining whether to deem approved 505(b)(2) biological products to be submitted under 351(a) or 351(k). Instead, FDA should adopt a case-by-case approach, which would be consistent with the intent of Congress, keep open the option for certain 505(b)(2) biological products sponsors to demonstrate interchangeability, and facilitate the availability of lower-cost, safe, and effective biological products for patients in need.
Sincerely,

Sincerely,



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