May 13, 2016

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

Re: ***Docket No. FDA–2015–D–4750***
Draft Guidance for Industry on Implementation of the "Deemed to be a License" Provision of the Biologics Price Competition and Innovation Act of 2009

Dear Sir or Madam:

Sanofi-aventis U.S. Inc., Genzyme Corporation, and Sanofi Pasteur SA, members of the Sanofi Group (Sanofi) appreciate the opportunity to respond to the Food and Drug Administration's (FDA's) Federal Register Notice of March 14, 2016, announcing the availability of draft guidance for industry entitled "***Implementation of the 'Deemed to be a License' Provision of the Biologics Price Competition and Innovation Act of 2009***" (Draft Guidance) and inviting public comment.[1]

A reasonable plan for implementing the "deemed to be a license" provision of the Biologics Price Competition and Innovation Act (BPCIA) is vital to Sanofi. Sanofi is one of the primary sponsors of insulin products both in the United States and globally. Insulin products now fall within the statutory definition of a "biological product." Sanofi presently has under development insulin and insulin-drug combination products that will be directly affected by the transition of insulin products to section 351 of the Public Health Service Act (PHSA). As an innovator in the field, Sanofi will be particularly impacted by the transition from one exclusivity and pre-market patent challenge system to another.

The issues presented by the "deemed to be a license" provision are complex and critically important. We appreciate the opportunity to participate in this guidance process and look forward to working with the agency to develop a framework for implementing the transition provision that is reasonable, administrable, and consistent with the law.

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[1] 81 FR 13373 (March 14, 2016).

I. THE DRAFT GUIDANCE

The Draft Guidance addresses three key areas of concern regarding transition products and the implementation of the "deemed to be a license" provision: (1) the status of existing Hatch-Waxman rights and exclusivities granted to transition products under the Food, Drug, and Cosmetic Act (FDCA), and of the patent listings in FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the *Orange Book*); (2) the effect on applications that are pending under section 505 and that remain unapproved as of the transition date; and (3) the availability of 12-year exclusivity under the PHSA for transition products. Under the Draft Guidance, as of the transition date, any approved drug applications for products that meet the definition of a biological product "will no longer exist" as new drug applications (NDAs) or abbreviated new drug applications (ANDAs). Draft Guidance at 5. Instead, they will immediately be replaced by approved biologics license applications (BLAs). *Id.*

According to the Draft Guidance, with respect to *Orange Book* listings – including patents and exclusivities for these products – the listings and existing Hatch-Waxman exclusivities will be terminated as of the transition date. Draft Guidance at 6. The agency takes the position that any exclusivity (3-year new use exclusivity, 5-year new chemical entity exclusivity, and pediatric exclusivity) and any remaining 30-month stay time must immediately be extinguished. The only exclusivity that will survive is 7-year orphan drug exclusivity because, under the agency's reasoning, it is capable of blocking approval of BLAs as well as NDAs and ANDAs. *Id.*

Further, any NDA or ANDA for a biological product that is either pending or tentatively approved as of March 23, 2020 will effectively be deemed withdrawn. Draft Guidance at 5-6. The Draft Guidance provides that the sponsor would have to resubmit the application under 351(a) or 351(k). *Id.* at 8-9.[2] Last, with regard to the availability of 12-year exclusivity, the Draft Guidance provides that a "deemed licensed" transition product will not be entitled to receive any amount of the 12-year exclusivity period allowed under section 351 for reference biological products. *Id.* at 6.

[2] This is likely to be of greatest concern and significance to sponsors of 505(b)(2) NDAs that are submitted prior to the transition date and which do not receive final approval before March 23, 2020. The Draft Guidance notes that 505(b)(2) sponsors may potentially submit a 351(a) application during the transition period, which is permitted under the statute; however, this would require a 505(b)(2) applicant to modify its development program to meet the requirements of a full BLA. *See* Draft Guidance at 8. Alternatively, the 505(b)(2) applicant could defer its application until after the transition date, and file it as a 351(k) application, provided it includes the data FDA would expect to see in a 351(k) application. *Id.* at 9. Unlike a 351(a) application, a 351(k) application could not be submitted prior to the transition date because such applications must reference an approved BLA.

II. COMMENTS

Comment One: FDA must take steps to preserve the value of regulatory exclusivity granted to sponsors under the FDCA and still in effect on March 23, 2020.

The FDCA unambiguously grants sponsors of approved NDAs periods of regulatory exclusivity to be applied against subsequent ANDAs and 505(b)(2) NDAs that seek to rely, in whole or in part, on FDA's finding of safety and effectiveness for a previously approved listed drug. These grants of exclusivity are vested rights that carry enormous economic value.

While the transition statute mandates that biological products approved under the FDCA must be transitioned to the PHSA, it does not grant FDA the authority to extinguish the value of the regulatory exclusivity and other rights that have been lawfully awarded to the sponsors of products approved under the FDCA. To revoke those rights without express statutory authority and without compensating the holder would be contrary to law. In particular, terminating the Hatch-Waxman exclusivity without compensating the holder would create a significant Fifth Amendment constitutional issue.[3] There is no evidence in the language of the transition statute that Congress intended to extinguish previously granted exclusivity awards. Nor is there language in the statute that evidences an intention by Congress to deny transition products the exclusivity rights that apply to all reference biological products.

FDA must implement the transition statute in a manner that gives effect to the intent of Congress, as evidenced by the language Congress enacted, and read in the context of the legislative debate leading up to enactment. As discussed below, in other contexts where Congress intended to impact exclusivity or patent listing rights under the FDCA, Congress was quite clear and express in doing so. This is consistent with the idea that fundamental constitutional issues are at stake when rights around proprietary data, exclusivity awards and patents may be impacted. FDA should reconsider its initial reading of the transition statute to avoid creating a constitutional issue that Congress itself did not intend to create. In fact, this would be straightforward under the clear and simple language of the transition statute: To avoid liability for lost Hatch-Waxman rights, FDA must recognize first licensure exclusivity for biological products approved under the

[3] The US Supreme Court has held that proprietary data submitted to a federal agency in support of a marketing application are protected by the Takings Clause of the US Constitution. *See Ruckelshaus v. Monsanto*, 467 U.S. 986, 1003-04 (1984). If the innovator-applicant submits data to the agency with a reasonable investment-backed expectation that both the data, and FDA's findings with respect to those data, will not be used directly to support the approval of another applicant's product, then use for that purpose could constitute a regulatory taking, triggering the need to compensate the owner. *Id.* at 1013-14. *See also Tri-Bio Laboratories, Inc. v. United States*, 836 F.2d 135, 140 (3d Cir. 1987). In this case, the rights accorded innovator sponsors under the Hatch-Waxman Act establish such an investment-backed expectation. Extinguishing those rights may therefore constitute a regulatory taking. Similarly, since enactment of the BPCIA, sponsors of NDAs for transition products have had a reasonable expectation of receiving the balance of reference product exclusivity upon being transitioned to the PHSA.

FDCA upon their transition to the PHSA as reference products under 351(a). This is discussed in greater detail in Comment Two below.

Comment Two: Biological products approved under the FDCA since the enactment of the BPCIA are eligible for the balance of 12-year reference product exclusivity.

The transition provision of the BPCIA does not contain statutory authority allowing FDA to terminate exclusivity for a reference product that has been approved under the FDCA and that is subsequently deemed to be a license under 351(a) of the PHSA. The agency appears to conclude that such products are ineligible for exclusivity for two reasons. First, the agency argues that 12-year exclusivity is only available for a product that is "first licensed" under section 351(a). The agency states that an application "deemed" to be licensed under section 351(a) for the first time is not "first licensed" under 351(a). Second, the agency claims that there is nothing in the BPCIA to suggest that Congress intended to award 12-year exclusivity to biological products previously approved as drugs, "some of which were approved decades ago," thereby resulting in windfall exclusivity "that would impede biosimilar or interchangeable product competition in several product classes until the year 2032." Draft Guidance at 7.

FDA's proposal to deny exclusivity to transition products is contrary to the statute and contrary to the intent of Congress to treat all biological products uniformly. The transition statute makes clear that all protein products previously regulated under the FDCA are – as of the date of enactment of the BPCIA – biological products, and therefore must be regulated as biological products under section 351 of the PHSA. Congress made an administrative allowance for these products with respect to the application process that would govern during the transition period.[4] The use of the NDA process for biological products during the transition period is an interim accommodation, with the NDA approval serving as a placeholder for the section 351(a) license until the transition date. In all other respects, as a legal, regulatory and scientific matter, transition products are biological products, including in their capacity to serve as reference biological products upon being transitioned to the PHSA as products licensed under 351(a).

Like any other reference product licensed under 351(a) since enactment of the BPCIA, transition products must be accorded a period of regulatory exclusivity. The PHSA, as amended by the BPCIA, defines "reference product" as "the single biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k)." 42 USC 262(i)(4). The statute then clearly provides that no biosimilar application may be approved "until the date that is 12 years after the date on which the reference product was first licensed under subsection (a)." 42 USC 262(k)(7)(A). This provision does not

[4] During the transition period, Congress specified that all applications for biological products "shall be submitted under section 351 of the [PHSA]," with the following exception: "An application for a biological product may be submitted under section 505 of the [FDCA]" provided that it is submitted "not later than the date that is 10 years after the date of enactment of [the BPCIA]." Pub. L. No. 111-148, § 7002(e)(1), (2).

concern the manner by which a reference product became licensed under 351(a). Rather it concerns the date upon which a reference product received marketing authorization. Because the exclusivity can only apply to reference biological products licensed under 351(a), the statute necessarily refers to the date the product was first licensed under that section simply to denote the starting date of the exclusivity period.

The fact that a prior approval of a biological product is "deemed to be a license" does not affect the date on which it was originally approved for purposes of exclusivity. As FDA has recognized, orphan drug exclusivity for a biological product approved under the FDCA will continue to remain in effect and, importantly, will run from the date of NDA approval. The NDA approval will remain operative for other purposes as well, as it must. For patent term extension, for example, review and approval of the NDA will continue to determine the calculation of time lost to regulatory review. The period of time in which an application for patent term extension must be submitted will also depend on the NDA approval date. We would also expect that periodic and annual reports will be based on the anniversary date of the NDA approval. Accordingly, when a transition NDA is deemed to be a BLA, there is no ambiguity or dispute as to the date of approval or the fact that the transition biologic was indeed "approved." The date of licensure for purposes of first licensure exclusivity is, very simply, the date of NDA approval.

As further confirmation of the intent of Congress, the statute expressly sets forth the conditions under which a product licensed under section 351(a) would not be considered "first licensed." 42 USC 262(k)(7)(C). These exemptions do not include a provision for products that are deemed to be a license. Had Congress intended to withhold exclusivity from transition products merely because they were transition products, it would have said so. For example, that is precisely what Congress did when it moved antibiotic products previously regulated under section 507 of the FDCA, to section 505 of the FDCA. Under section 125 of the Food and Drug Administration Modernization Act of 1997 (FDAMA), all applications previously approved under section 507 were deemed to be approved under section 505. The statute then expressly exempted these products from the patent listing, patent certification, and exclusivity provisions of the FDCA.[5]

In contrast, the BPCIA in no way denies exclusivity to products that become "reference products" by virtue of being "deemed to be a license." There is no indication in the statute – as there was, for example, with the antibiotic transition provisions – that Congress intended to deny

[5] Specifically, FDAMA 125(d)(2) exempts an antibiotic application from Hatch-Waxman benefits when "the drug that is the subject of the application contains an antibiotic drug and the antibiotic drug was the subject of an application" received by FDA under section 507 of the FDCA before the enactment of FDAMA. Accordingly, applications for antibiotic drugs received by FDA under section 507, prior to the enactment of FDAMA, were not subject to Hatch-Waxman rights and obligations upon being deemed approved under section 505. Likewise, applications subsequently submitted to FDA under section 505 for drugs that contain an antibiotic drug that was the subject of an application under 507 were exempt from Hatch-Waxman rights and benefits.

exclusivity to such products. [6] Rather, Congress enacted a framework in the transition statute that requires all biological products to be consolidated under one regulatory scheme and to be treated consistently. Accordingly, if a biological product approved under section 505 is deemed to be a reference product, *i.e.*, deemed to be "licensed under subsection (a)" of the PHSA, then it should be awarded the exclusivity that the statute requires. Just as FDA has applied the remainder of the 12-year period to the PHSA biologics approved before the enactment of the BPCIA, it should apply the remainder of the 12-year period to biological products approved under section 505 of the FDCA when those products are deemed to be reference products.

Specifically, after a transition product is deemed a license under 351(a), it should be listed in FDA's publication, *List of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations* (the *Purple Book*), showing (1) date of first licensure conforming to the date of the original NDA approval, and (2) a reference product exclusivity expiry date that is 12 years after the date of original NDA approval. Accordingly, FDA should refrain from filing a biosimilar application referencing that product until 4 years after the date of first licensure, and it should not approve any biosimilar license application until the reference product exclusivity has expired. 42 USC 262(k)(7)(A), (B).

This does not, as FDA asserts, provide windfall exclusivity to products approved "decades ago," nor does it stifle biosimilar or interchangeable competition "until the year 2032." Draft Guidance at 7. It is merely consistent treatment of all biological products, as Congress intended when it directed that all biological products should be unified under one regulatory scheme.

Comment Three: FDA should implement measures to accord pediatric exclusivity to biological products previously regulated under the FDCA that are deemed to be reference products licensed under 351(a) of the PHSA.

Any product previously regulated under the FDCA that is deemed to be a reference product under 351(a), and that is eligible for reference product exclusivity in accordance with Comment Two above, should also be accorded pediatric exclusivity under section 351(m) of the PHSA, provided that the sponsor previously had an existing grant of pediatric exclusivity in effect under the FDCA. The provisions of PHSA 351(a) and FDCA 505A are virtually identical in terms of the procedures and requirements for securing pediatric exclusivity. Accordingly, if the sponsor of the biological product received pediatric exclusivity under the FDCA, it should have that previous grant recognized as an extension to its reference product exclusivity in accordance with PHSA 351(k)(7) and (m). Specifically, if a transitioned biological product is deemed to be a

[6] Under the Draft Guidance, a transition product could be approved under FDCA 505(b)(1) on March 22, 2020, and effectively denied all regulatory exclusivity. A 351(k) biosimilar application could be filed referencing that product the very next day. While this is an extreme example, it serves to illustrate that Congress could not have intended FDA to deny regulatory exclusivity to biological products approved under the FDCA, without expressly authorizing such an outcome.

license under 351(a), the periods of exclusivity referred to in 351(k)(7) should be deemed to be 4 years and 6 months rather than 4 years, and 12 years and 6 months rather than 12 years.

Comment Four: The Draft Guidance should be revised to address drug/biologic combination products, and should recognize that the drug component of the combination product must retain exclusivity and *Orange Book* rights authorized under the FDCA.

Several drug/biologic combination products are either approved, pending, or currently under late stage development for submission, review and approval under section 505 of the FDCA. For drug/biologic combination products that are approved or will be approved under NDAs during the transition period, it is possible that – if FDA considers the primary mode of action for such a product to be attributed to the transition biologic component – the approved NDA for the combination product may in its entirety be "deemed to be a license" as of March 23, 2020. If that were to be the case, then under the Draft Guidance all Hatch-Waxman rights and exclusivities would be extinguished on the transition date. In addition, the Draft Guidance would require that all listings for such products in the *Orange Book* would be removed, and all rights and obligations associated with the listed patent information would immediately terminate.

For Sanofi, this issue is not theoretical. We currently have pending with FDA a 505(b)(1) application for a fixed-dose lixisenatide/insulin glargine, drug/biologic combination product. We expect to obtain approval before the transition date. We also are anticipating that the lixisenatide component will be granted 5-year NCE exclusivity, that a balance of this exclusivity will be unexpired on March 23, 2020, and that one or more patents claiming, among other things, the drug substance, will be listed in the *Orange Book.*

The transition provision of the BPCIA does not provide FDA with the authority to deny the approved drug product, *i.e.*, the drug product component of the combination product, rights that have been accorded to it under the FDCA. FDA must address this issue in its implementation of the transition statute. One approach the agency must consider would be to administratively separate the NDA-approved drug/biologic combination product into an NDA and a BLA, *i.e.*, an approved NDA for the drug component of the combination product and a licensed biologic for the biological product component of the combination for use with the individually specified drug. In this way, the drug component of the combination product, such as Sanofi's pending lixisenatide/insulin glargine combination, would remain an approved drug under FDCA 505 with corresponding exclusivity and patent listings.[7]

[7] FDA will be required to address these issues for drug/biologic products that will be submitted after the March 23, 2020 transition date as well. It will therefore be necessary for FDA to articulate a framework for regulating such products, to determine under what conditions Hatch-Waxman rights and exclusivities can be recognized for the drug component.

We recognize this is a particularly complex issue and we anticipate that FDA may need to address it through further proposals and elicitation of comments from affected stakeholders. The lixisenatide/insulin glargine combination represents a new kind of combination product, in effect created by the change in status of insulin from an FDCA drug component to a biological product. How such combinations are regulated may depend in part on how FDA ultimately resolves the broader issues of reference product exclusivity for transition products.

Comment Five: FDA must refrain from making therapeutic equivalence determinations for transition biological products that will be deemed licensed.

The standard for the assignment of an A-level therapeutic equivalence rating in the *Orange Book*[8] is markedly different from the standard for determining the interchangeability of two biological products under section 351(k) of the PHSA. Therapeutic equivalence ratings generally are based on a finding of pharmaceutical equivalence and bioequivalence, where the active ingredients in both products are found to be identical. *See* 21 CFR 320.1(c). Such a finding likely cannot be made for two protein products, even those that have historically been regulated as drugs. As Congress recognized in enacting the BPCIA, protein products may be found "highly similar," but they are not expected to be considered "identical."

As of March 23, 2010, when the BPCIA was signed into law, all categories of protein products approved under the FDCA were determined to be biological products henceforth to be regulated under the PHSA. Although biological products may, during the transition period, still be approved under section 505 of the FDCA, this is an interim measure put in place by Congress with a directive that these products be deemed to be licensed under the PHSA on March 23, 2020. Thus, while biological products may still be submitted and approved under NDAs in lieu of being licensed, this in no way diminishes their status -- both under the law and as a matter of science -- as biological products.

The therapeutic equivalence ratings system, in contrast, is expressly reserved for drugs regulated under the FDCA and is inapplicable to biological products. There is no provision for therapeutic equivalence ratings under the PHSA. The standards that apply to a finding of "interchangeability" are different from those that apply to a finding of therapeutic equivalence, and the findings carry different implications.[9] Moreover, when the therapeutic moiety is a

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[8] Therapeutic equivalence ratings are published in the *Orange Book*. All drug products that are "pharmaceutically equivalent" to each other (same active ingredient, strength, route of administration and dosage form) are considered "multi-source" and are automatically assigned an equivalence rating. If two pharmaceutically equivalent drugs have been shown to be bioequivalent to each other, they will receive an "A-rating." If the agency lacks evidence of bioequivalence, the product will be assigned a "B-rating." The effect of an A-rating in the *Orange Book* is that, in most states, a generic drug may be automatically substituted for the prescribed reference product at the pharmacy.

[9] Also note that therapeutic equivalence ratings are not a statutory component of the approval process under section 505 and are therefore not required. While the regulatory findings needed to assign a therapeutic equivalence rating follow directly from the approval of an ANDA under section 505(j), that is not the case under 505(b)(2).

protein, therapeutic equivalence is confounded by the lack of a reasonable scientific basis for saying that the active ingredients in two drug products are "the same." As FDA recognized in approving Basaglar (insulin glargine) under 505(b)(2), "[t]he assessment of pharmaceutical equivalence for a recombinant or biologically-derived product and/or protein or peptide product is complex."[10] Accordingly, FDA concluded that Basaglar has no pharmaceutical equivalent.[11]

Sanofi therefore urges FDA to continue to refrain from assigning therapeutic equivalence ratings to transition products approved under section 505 of the FDCA for the remainder of the transition period.

Comment Six: "Deemed to be a license" BLAs should not be eligible for an "interchangeability" finding under the PHSA without a separate application and approval under section 351(k).

Any transition product that is deemed to be a license should not be eligible for a finding of interchangeability with any other biologic product without a new application under 351(k) seeking a determination of interchangeability in accordance with the proper statutory process and standards.

Congress adopted a specific standard for making a determination of interchangeability for biosimilar products licensed under section 351(k), and additional standards for interchangeable products that are intended for use on a repeat or chronic basis. *See* 42 USC 262(k)(3) and (4). These standards require a demonstration of comparative safety and efficacy that is not required for the assignment of therapeutic equivalence ratings in the *Orange Book*. The standards for interchangeability are instead specifically tailored to the complexity of biological products and the potential risks associated with administering versions of "highly similar" biologics to the same patient.

Accordingly, in keeping with the goal of the BPCIA to consolidate all biological products under one approval statute and to regulate them consistently, any biological product that is "deemed to be a license" should be ineligible to be approved as an interchangeable biosimilar

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Highlighting this issue, FDA recently revised the preface to the Orange Book to indicate that sponsors seeking therapeutic equivalence evaluations for products approved under 505(b)(2) may need to submit a citizen petition to obtain such a result. *Orange Book*, 36th Edition, Preface at xxiii ("A person seeking to have a therapeutic equivalence rating for a drug product approved in a 505(b)(2) application may petition the Agency through the citizen petition procedure.").

[10] Approval Package, NDA 205692, Other Reviews, 505(b)(2) Assessment at 4.

[11] *Id.*

product without a separate application and a specific finding of interchangeability by FDA under section 351(k).[12]

Comment Seven: FDA should allow sponsors of affected applications currently under review as 505(b)(1) NDAs the option to administratively move the application to a PHSA 351(a) application without penalty or additional review time.

Because Congress enacted within the BPCIA an option for sponsors of transition products in development to choose whether to submit applications under the FDCA or PHSA, this option should remain open, particularly now that FDA has articulated a framework in the Draft Guidance that potentially may otherwise disadvantage such sponsors. Although sponsors have had this option since enactment of the BPCIA, FDA has not previously advised sponsors that biological products approved under FDCA could lose statutorily provided regulatory data protection and Hatch-Waxman patent litigation procedures, both of which contribute to market exclusivity under the FDCA. Because the Draft Guidance was issued with four years remaining in the transition period, products under current review may be acutely affected. FDA should allow the administrative transfer of these applications, without penalty or delay, to the PHSA. Upon sponsor request, applications pending under 505(b)(1) should be deemed unapproved 351(a) applications. Within FDA's current review structure, this is a purely administrative measure, without any effect upon substantive review or staffing. Providing this option fulfills the intent of the transition statute to enable products regulated under one statutory framework to be transitioned to another with minimal disruption.

Comment Eight: FDA's proposals under the Draft Guidance must proceed through notice and comment rulemaking.

Under the current Draft Guidance, FDA proposes to expunge the *Orange Book* listings for transition products and to immediately terminate any 3-year and 5-year exclusivity (along with pediatric exclusivity), and any remaining 30-month stay time. Further, any application under the FDCA for a biological product that is either pending or tentatively approved as of the transition date will in effect be deemed withdrawn and would likely need to be resubmitted under 351(a) or 351(k). Last, FDA provides that a "deemed licensed" transition product will not be eligible for any amount of the 12-year exclusivity period allowed under section 351 for reference biological products.

These proposals affect legal rights of such magnitude that notice and comment rulemaking is required. If FDA advances these proposals without rescinding or significantly modifying them, and continues to proceed through the guidance process, it will severely jeopardize the legitimacy

[12] FDA has not yet released any guidance on how a biosimilar sponsor may address the standard of interchangeability enacted by the BPCIA.

of its actions. While the agency may maintain that the guidance process "does not establish any rights for any person and is not binding on FDA or the public," that is decidedly not the case here. Whether or not the agency finalizes the draft guidance, transition products will be deemed to be BLAs on March 23, 2020, and the agency's actions at that time will result in apparently binding legal effects. Notice and comment rulemaking is required to vest these actions with legitimacy and to build consensus around the agency's proposals for implementing the transition statute.

III. CONCLUSION

Congress enacted the BPCIA to benefit patients by facilitating competition in the field of biological medicine while maintaining incentives for the development of new biological products. FDA's Draft Guidance contains proposals that conflict with these goals and would promote entry of follow-on products and competition at the expense of the incentives Congress expressly provided. For these reasons, Sanofi respectfully asks FDA to revise the Draft Guidance in a manner consistent with our comments above.

Respectfully submitted,

Linda Bowen

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