May 13, 2016

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; Implementation of the "Deemed to be a License" Provision of the Biologics Price Competition and Innovation Act of 2009; Comments of the Generic Pharmaceutical Association (GPhA) and the Biosimilars Council

Dear Sir or Madam:

The Generic Pharmaceutical Association ("GPhA") and the Biosimilars Council are pleased to submit comments to the Food and Drug Administration's ("FDA's") draft guidance for industry on Implementation of the "Deemed to be a License" Provision of the Biologics Price Competition and Innovation Act of 2009 ("BPCIA") ("Draft Guidance"). *See* 81 Fed. Reg. 13373 (March 14, 2016) (Docket No. FDA-2015-D-4750). Although GPhA agrees with many aspects of the Draft Guidance, GPhA is concerned that FDA's proposed policy with respect to pending applications under Section 505 that are not approved by March 23, 2020 is contrary to the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 Federal Food, Drug, and Cosmetic Act ("FFDCA"). **Because FDA's proposed policy will impair patient access to affordable alternatives to these important brand name biologics contrary to Congressional intent, GPhA respectfully requests that FDA amend its policy to facilitate a streamlined transition for both approved and pending applications.**

GPhA 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 88% of all prescriptions dispensed in the U.S., but only 28% of expenditures on prescription drugs. GPhA is the sole association representing America's generic pharmaceutical sector in the United States. The GPhA Biosimilars Council, a division of GPhA, works to ensure a positive regulatory, reimbursement, political and policy environment for biosimilar products, and will educate the public and patients about the safety and effectiveness of biosimilars. Areas of focus include education, access, the nascent regulatory environment, reimbursement and legal affairs. Member organizations include any company or stakeholder organization working to develop biosimilar products with the intent to compete in the U.S. market. While this letter represents the views of GPhA and our Biosimilars Council, the comments may not reflect the positions of all member companies.

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I. GPhA Generally Supports FDA's Proposal for the Transition of Approved Applications

In its Draft Guidance, FDA states that on March 23, 2020, applications for biological products approved under section 505 of the FFDCA will be considered approved Biologics License Applications ("BLAs") under section 351(a) or 351(k) of the Public Health Service Act ("PHS Act"), as appropriate.[1] FDA further states that any pre-existing exclusivity period (other than orphan drug exclusivity) or listed patent would "cease to have any effect" and would "no longer be relevant for purposes of determining the timing of approval of a 505(b)(2) application (or ANDA)."[2] Finally, FDA states that biologics that are "deemed" to have approved BLAs "will not receive a period of exclusivity under section 351(k)(7)(A) and (B) of the PHS Act" because they are not "first licensed" under the PHS Act.[3]

GPhA agrees that, under the clear statutory language, approved New Drug Applications (NDAs) and Abbreviated New Drug Applications (ANDAs) for biological products must be treated as approved BLAs on and after March 23, 2020.[4] GPhA also agrees that such BLAs are 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. This is because, as FDA explains, such products are not "first licensed" under the PHS Act but are instead "deemed" to be licensed by operation of section 7002(e)(4) of the BPCIA. Moreover, 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 proposed policy to deny exclusivity to such products is thus sound on both public policy and legal grounds.[5]

[1] Draft Guidance, at 5.
[2] Draft Guidance, at 6.
[3] Draft Guidance, at 6.
[4] As discussed further below, GPhA disagrees that FDA cannot, as an administrative matter, treat such an application as both a BLA and an NDA after March 23, 2020, if there is a pending 505(b)(2) application or ANDA that relies upon it as a listed drug.
[5] GPhA also agrees that there is no basis for FDA to transfer unexpired exclusivity periods, other than orphan drug exclusivity, from a listed drug approved under Section 505 of the FFDCA to a reference drug "deemed" to have an approved BLA after March 23, 2020.

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II. FDA Must Adopt a Policy for Pending Applications That Does Not "Have a Significant Impact on Development Programs" for Proposed Protein Products

In its Draft Guidance, FDA states that it "will not approve any application under section 505 of the FD&C Act for a biological product subject to the transition provisions that is pending or tentatively approved 'on' March 23, 2020."[6] FDA acknowledges that "this interpretation could have a significant impact on development programs for any proposed protein products intended for submission under section 505 of the FD&C Act that are not able to receive final approval by March 23, 2020."[7] FDA also acknowledges that the BPCIA explicitly permits sponsors to submit NDAs and ANDAs for protein products in certain circumstances "not later than" March 23, 2020.[8] Because FDA's proposed policy for pending applications submitted under section 505 for biologics: (a) will severely impair patient access to affordable alternatives to transitioned brand name biologics, and (b) is contrary to the clear statutory language of the BPCIA permitting the submission of NDAs and ANDAs for transitional biologics, GPhA respectfully requests that FDA amend its proposed policy to facilitate a streamlined transition for pending applications in a manner that minimizes the impact on ongoing development programs and gives effect to all provisions of the BPCIA.

A. FDA's Proposed Policy for Pending Applications Will Have a "Significant Impact" on Ongoing Development Programs That Will Severely Impede Patient Access to Affordable Biologics, Contrary to Congressional Intent

FDA must amend its proposed policy regarding pending applications because it erects unnecessary roadblocks to the development of transitional biologics that will significantly delay the approval and availability of lower-cost, safe and effective biological products for patients in need. As FDA itself admits, its proposal could have a "significant impact" on ongoing development programs for important transitional biologics, such as insulin and human growth hormone. FDA's policy thus has the potential to add billions of dollars of unnecessary costs to the U. S. healthcare system with no countervailing public health benefit. The only beneficiaries of FDA's proposal, in fact, will be the sponsors of brand name transitional biologics, who will continue to reap monopoly profits during the unnecessary delays caused by FDA's proposed policy. This clearly runs counter to one of the main purposes of the BPCIA, which is to increase patient access to safe, effective and affordable biosimilar and interchangeable biological products.

FDA's proposed policy regarding pending applications will impede the timely approval of competing products in several ways. First, FDA's proposed policy will interrupt ongoing review activities for pending applications in a manner that will be highly disruptive and cause unnecessary delays. According to FDA, pending applications that have not been approved by FDA by March 23, 2020 will never be approved under section 505 and thus will need to be

[6] Draft Guidance, at 5.
[7] Draft Guidance, at 6.
[8] Draft Guidance, at 5.

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"withdrawn and resubmitted under section 351(a) or 351(k) of the PHS Act, as appropriate."[9] This proposed requirement applies not only to newly submitted applications but also to applications that are nearing approval and for which extensive review activities have been undertaken. Indeed, FDA's proposal even applies to pending applications *for which FDA's scientific review is complete and that have been tentatively approved.* Requiring such applicants to withdraw their applications and submit new ones under section 351(a) or 351(k) of the PHS Act will delay the approval of such products by: (1) requiring sponsors to prepare new submissions, which can be time-consuming, especially if different or additional data are required; (2) restarting duplicative review processes (*i.e.*, "reinventing the wheel"); and (3) imposing new PDUFA or BsUFA review deadlines, which could extend the review timeline by an additional 10 months or more.

Second, FDA's proposed policy will force sponsors who are ready to submit applications for lower-cost biologics prior to March 23, 2020 to delay their submissions until after March 23, 2020, thereby significantly delaying the review, approval and availability of biological products that compete with expensive brand name biologics. For example, if a sponsor is ready to submit a 505(b)(2) application or ANDA for a transitional biologic in June 2019, FDA's proposed policy would provide a strong incentive for the sponsor to forgo any submission at that time because of the meaningful possibility that the application would not be approved prior to March 23, 2020 (and thereafter would have to be withdrawn and re-submitted as a BLA). FDA's policy, however, also would make it impossible for the sponsor to submit a biosimilar application prior to March 23, 2020 because, until that date, there would be no "reference product" upon which the sponsor could rely. As FDA admits, a 505(b)(2) applicant seeking to modify its development program could not submit a biosimilar application until "such time as there is a biological product licensed under section 351(a) of the PHS Act that could be a reference product."[10] FDA's proposed policy thus creates a regulatory "dead zone" of a year or more between the time no rational sponsor would submit a 505(b)(2) application or ANDA (because of the likelihood it would not get approved in time) and the first date a biosimilar application could be submitted (*i.e.*, March 23, 2020).[11]

The delays caused by this regulatory "dead zone" not only will have a "significant impact" on ongoing biosimilar development plans but also will have a major negative impact on the U.S. healthcare system. For example, in the insulin market alone, FDA's proposed policy could result in $6.65 billion lost savings per year to the U.S. healthcare system. Sanofi's Lantus and Lantus Solostar products are daily, chronic use medications widely prescribed to a growing population diagnosed with diabetes. In the year ending in October 2015 alone, Sanofi Aventis realized almost $9 billion dollars in sales – much of which was borne by state and federal drug purchase and insurance programs – and the price is skyrocketing. According to a recent article

[9] Draft Guidance, at 6.
[10] Draft Guidance, at 8.
[11] While sponsors theoretically could submit full BLAs prior to March 23, 2020, this would entail additional delays since sponsors would be required to obtain or generate a full data package to support approval of a full BLA. Thus, the delays inherent in this pathway may be even greater than those associated with a biosimilar application.

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in the Philadelphia Inquirer, the price of Lantus rose 22.7 percent from 2014 to 2015.[12] This increase was on top of two significant price increases implemented in 2013.[13] A biosimilar or interchangeable insulin product approved to compete with the Lantus products can result in *$18.3 million in daily savings* to the U.S. healthcare system.

B. FDA's Proposed Policy for Pending Applications Is Inconsistent with the Plain Language of the BPCIA

GPhA respectfully requests that FDA amend its proposed policy for pending applications for the additional reason that it is contrary to the plain language of the BPCIA and Congress' overall goal of expediting patients' access to needed medicines. An agency's interpretation of a statute it is responsible for implementing generally is subject to a two-step review process by the federal courts.[14] Under step one, a court must determine "whether Congress has directly spoken to the precise question at issue."[15] If a court determines, using traditional tools of statutory construction, that "the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress."[16] The most powerful indicators of Congressional intent are the statutory language itself and the structure and purpose of the statute as a whole.[17] Moreover, it is a bedrock principle of statutory construction that a provision cannot be read in isolation but instead must be interpreted in context, taking into account the entire statutory scheme.[18]

In this case, FDA's interpretation is impermissible because it ignores the clear statutory language explicitly permitting a sponsor to submit an application for a biological product under section 505 of the FFDCA up until March 23, 2020, the transition date. Under FDA's interpretation, the March 23, 2020, date become inoperative and superfluous, since an application submitted under section 505 of the FFDCA close to that date could not be approved and would need to be withdrawn and resubmitted under section 351(a) or 351(k) of the PHS Act. An interpretation of a statute that renders any provision inoperative and superfluous, however, contravenes well established rules of statutory construction and must be rejected.[19]

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[12] *Insulin Price Shock*, David Sell, Philadelphia Inquirer (Jan. 3, 2016).
[13] *U.S. Insulin Prices Rise As Sanofi, Novo Await Rivals*, Trista Kelley, Bloomberg News (Aug. 15, 2013) (reporting on a nearly 15% price increase in August 2013 following a 10% price increase in April of the same year).
[14] *Chevron, U.S.A., Inc. v. Natural Resources Def. Council, Inc*, 467 U.S. 837, 842-843 (1984), *reh'g denied*, 468 U.S. 1227 (1984).
[15] *Id*. at 842.
16 *Id*. at 842-843; *see also Carcieri v. Salazar*, 555 U.S. 379, 387 (2009) (explaining how, if the statutory language is "plain and unambiguous," the court must "apply the statute according to its terms").
[17] *See Amalgamated Transit Union v. Skinner*, 894 F.2d 1362, 1368 (D.C. Cir. 1990) (quoting *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 291 (1988)).
[18] *Robinson v. Shell Oil Co.*, 519 US 337 (1997); *Stat-Trade Inc. v. FDA*, 869 F. Supp. 2d 95, 102 (D.D.C. 2012); *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1319 (D.C. Cir. 1998).
[19] *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 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

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FDA contends that its interpretation does not ignore this statutory provision because sponsors may submit 505(b)(2) applications and ANDAs up until March 23, 2020. The problem with this explanation, however, is that FDA also states that it will not approve any such application after March 23, 2020. As a practical matter, therefore, sponsors are foreclosed from submitting applications close to the transition date because, under FDA's interpretation, FDA approval would be a regulatory impossibility. For example, even though Congress explicitly permits a sponsor to submit a 505(b)(2) application for a protein product on March 21, 2020 (*i.e.*, just two days before the transition date), under FDA's interpretation, it would be futile to do so because such an application could never be reviewed and approved by FDA within two days.[20] Congress, however, does not create regulatory pathways that are inherently futile.[21] It thus is not reasonable for FDA to interpret the BPCIA transition provision in a way that explicitly permits sponsors to submit applications under section 505 even though those applications can never be approved (and that must be withdrawn and re-submitted after March 23, 2020).

FDA's interpretation also is inconsistent with the structure and purpose of the BPCIA. One of the primary goals of the BPCIA is to increase the availability of affordable biologics to American consumers. The BPCIA accomplishes this by, among other things, creating an abbreviated approval pathway for biosimilars and interchangeable biological products that can result in more streamlined development programs. By creating a regulatory "dead zone" as described above, however, FDA's proposed interpretation runs directly contrary to these goals. It not only will disrupt and delay ongoing biosimilar development programs for transitional biological products, but it also will unnecessarily delay the submission, review and approval of applications for affordable biological products that can compete with the brand name products.

Consequently, in order to make operative the statutory provision allowing the *submission* of 505(b)(2) applications and ANDAs until March 23, 2020, FDA must interpret the BPCIA transition provisions in a way that also allows *approval* of such applications without undue disruption or delay, including approvals after March 23, 2020.

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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.").

[20] Under PDUFA, standard reviews of NDAs typically take at least 10 months and even expedited reviews are targeted at six months. *See PDUFA Goals Letter for Fiscal Years 2013 through 2017*, p. 4. Congress was well aware of these review timelines when it passed the BPCIA transition provisions.

[21] *Nixon v. Missouri Municipal League*, 541 U.S. 124, 138 (2004) ("Court will not construe a statute in a manner that leads to absurd or futile results") (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)).

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C. FDA Should Approve Pending Applications Without Requiring Withdrawal and Resubmission

There are several ways FDA could implement the BPCIA transition provisions with respect to pending applications in a manner that is consistent with the statutory language and with past precedent. For example, FDA could simply "deem" a pending application submitted under section 505 of the FFDCA to be a pending BLA submitted under section 351(a) or 351(k) of the PHS Act and continue to review such applications without interruption in a seamless fashion. GPhA believes that this interpretation not only is more consistent with the clear statutory language and intent of the BPCIA, but also is less burdensome to sponsors, FDA and the marketplace in general and thus will result in more timely approvals of competing biological products.[22]

Although there is no explicit provision in the BPCIA authorizing this action, FDA has ample authority under the FFDCA and PHS Act to treat one type of pending application as a different type of pending application. FDA, in fact, has exercised this inherent administrative authority numerous times in similar situations in the past. For example, when section 507 of the FFDCA was repealed in 1997, FDA deemed pending antibiotic applications submitted under that section to be pending applications under section 505 of the FFDCA. In that case, like here, the statutory transition provision addressed only "approved" applications, not pending applications.[23] The absence of explicit statutory authority regarding pending 507 applications, however, did not stop FDA from deeming them to be pending section 505 applications as an administrative matter. Significantly, FDA did not require pending 507 applications to be withdrawn and resubmitted under section 505, and thus accomplished the transition with minimal disruption and delay.[24]

Likewise, in 1997, FDA deemed a pending premarket approval application ("PMA") for an ultrasound contrast agent to be a "submitted and filed NDA under section 505(b) of the Act."[25] Again, FDA did not require the applicant to withdraw its PMA and submit a new NDA under section 505 of the FFDCA. Rather, FDA simply assigned the application a new NDA number, transferred the review from the Center for Devices and Radiological Health ("CDRH")

[22] FDA also could interpret the BPCIA transition provision to allow pending 505(b)(2) applications and ANDAs to continue to be reviewed and approved under section 505 of the FFDCA. For example, FDA could treat the transition of the reference drug from an NDA to a BLA as involving the withdrawal of the NDA. Under the FFDCA and FDA regulations, 505(b)(2) applications and ANDAs can continue to rely upon a withdrawn NDA as the listed drug unless the application has been withdrawn for safety or effectiveness reasons. *See* 21 C.F.R. §§ 314.127(a)(9), (10), (11). Upon approval, FDA could then "deem" the approved 505(b)(2) applications and ANDAs to be approved 351(k) applications, either under authority of the BPCIA or as an exercise of FDA's inherent administrative powers.

[23] Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 125(d) (1997).

[24] FDA Guidance, *Repeal of Section 507 of the Federal Food, Drug, and Cosmetic Act*, p. 5 ("All action letters must use the 505(b) or 505(j) templates, even for drugs that originally were submitted under section 507, but are the subject of Agency action on or after November 21, 1997.").

[25] 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").

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to the Center for Drug Evaluation and Research ("CDER") and continued its review of the application without interruption. FDA explained its process this way:

> CDER will review the application under the statutory and regulatory standards applicable to new drug products, *see* 21 USC 505(d) and 21 CFR 314.125(d). CDER will not, however, repeat the review of those portions of the PMA on which CDER officials have already completed substantial work. Moreover, CDER will be able to rely, as appropriate, on the extensive analyses already done by CDRH, the comments and recommendations of the February 24, 2997, advisory panel, and any conclusions already reached by CDRH officials regarding the data and information in the PMA.[26]

Moreover, FDA decided that the "goal date" for the application under the Prescription Drug User Fee Act ("PDUFA") would run from the date the application was initially filed as a PMA, not the date it was "deemed" to be an NDA.[27]

FDA's overriding goal in the above situations was to "ensure 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."[28] For ultrasound contrast agents, for example, FDA explained that its re-designation from a PMA to an NDA could be accomplished "without a significant interruption in the pre-market review process" because the review standards for drugs and devices are similar and CDER review staff already had familiarity with the pending application.[29] Moreover, FDA concluded that any slight differences in the requirements of a PMA versus an NDA could be handled through submission of an amendment to the pending NDA following the re-designation.[30]

GPhA respectfully requests that the agency adopt a similar strategy in this case, one that minimizes disruption and prejudice in the marketplace and, unlike FDA's current proposal, does not have a "significant impact" on ongoing biosimilar development. Indeed, the same factors that were present in the transition of ultrasound contrast agents apply with equal or greater force here. For example, the standards for approval of a 505(b)(2) application for a protein product are highly analogous to the standards for approval of a biosimilar application. A 505(b)(2) application, like a biosimilar application, relies upon a reference product for approval and may be supported by one or more clinical studies establishing safety and/or effectiveness (including immunogenicity). In addition, the 505(b)(2) process has been used to approve proteins based

[26] Consolidated Response, at 59-60.
[27] Consolidated Response, at 59.
[28] Consolidated Response, at 59.
[29] Consolidated Response, at 60.
[30] Consolidated Response, at 60.

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upon the same "highly similar" standard used for biosimilar applications.[31] Finally, by operation of the statute, biosimilar applications must be reviewed by the same review division that reviewed the reference product.[32] Accordingly, the division responsible for reviewing a 505(b)(2) application for a protein product will be the same one that is responsible for reviewing a biosimilar application after the transition.

For the reasons discussed above, GPhA thus respectfully requests FDA to amend its proposed policy regarding pending applications and instead adopt a 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) 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.

III. Conclusion

For the reasons set forth above, GPhA supports FDA's proposed policy regarding approved biological products subject to the BPCIA transition provision, including FDA's position that such products are not eligible for 4- and 12-year exclusivity under the BPCIA. However, GPhA believes FDA's proposed policy regarding *pending* applications is inconsistent with the plain language of the BPCIA and should be amended. By creating a regulatory "dead

[31] For example, Omnitrope® (somatropin [rDNA orgin] for injection) was approved based upon a showing that its somatropin active ingredient is "highly similar" to the somatropin in the reference product. FDA Response to Omnitrope Petition, Docket No. FDA-2004-P-0339, at 14 (May 30, 2006) ("Omnitrope Petition Response"). This is the same standard used to approve biosimilar applications. 42 U.S.C. § 262(i)(2).
[32] 42 U.S.C. § 262(k)(5)(B).

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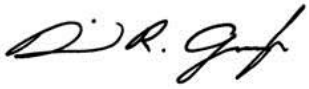
zone" for pending applications, FDA's proposed policy would have a "significant impact" on ongoing development programs for proposed protein products that, in turn, will impede patient access to affordable alternatives to these important brand name biologics, contrary to Congressional intent.

Instead of adopting a policy that, by the Agency's own admission, severely impacts the marketplace, FDA should implement policies that "ensure 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." GPhA respectfully suggests that "deeming" an application submitted under section 505 of the FFDCA to be a BLA submitted under section 351(a) or 351(k) of the PHS Act, as appropriate, accomplishes this important goal in a way that is consistent with both the clear statutory language and the intent of Congress to facilitate the availability of lower-cost, safe and effective biological products for patients in need.

Sincerely,



David R. Gaugh, R.Ph.
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