October 27, 2015

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

Re: Docket No. FDA-2015-N-0648: Designation of Official Names and Proper Names for Certain Biological Products; Proposed Rule, 80 Fed. Reg. 52224 (Aug. 28, 2015); Docket No. FDA-2013-D-1543: Nonproprietary Naming of Biological Products: Draft Guidance for Industry; Notice, 80 Fed. Reg. 52296 (Aug. 28, 2015)

Dear Sir or Madam:

Janssen Pharmaceutical Companies of Johnson & Johnson (Johnson & Johnson or the Company) is pleased to provide comments on two related proposals released by the Food and Drug Administration (FDA or the agency) that would designate distinguishable nonproprietary names for biologics: (1) the above-referenced proposed rule,[1] which would add distinguishable suffixes to the nonproprietary names of six currently marketed biologics; and (2) FDA's Draft Guidance for Industry, entitled "Nonproprietary Naming of Biological Products" (Draft Guidance),[2] which outlines the agency's proposed policy for designating distinguishable nonproprietary names for all biologics.

As a global leader in biotechnology, Johnson & Johnson has a valuable perspective at a time when the U.S. market is expanding to include FDA-approved biosimilars for the first time. We have many years of experience with the development, manufacture, and postmarketing monitoring of biologics. Our biologics portfolio spans immunology, cardiovascular disease, and oncology and includes ORTHOCLONE OKT3® (muromonab-CD3), the first monoclonal antibody ever approved; PROCRIT® (epoetin alfa); REMICADE® (infliximab); REOPRO® (abciximab); SIMPONI® (golimumab); SIMPONI® ARIA™ (golimumab); STELARA® (ustekinumab); and SYLVANT® (siltuximab).

Johnson & Johnson welcomes FDA's proposal to require distinguishable nonproprietary names for all biologics. FDA's proposal is in accord with the Citizen Petition submitted by Johnson & Johnson in 2014 (Citizen Petition), which requested that FDA require nonproprietary names for biosimilars that are similar to, but not the

[1] 80 Fed. Reg. 52224 (Aug. 28, 2015); FDA, Guidance for Industry: Nonproprietary Naming of Biological Products (Draft) (Aug. 2015) (Draft Guidance).

[2] 80 Fed. Reg. 52296 (Aug. 28, 2015).

same as, those of their reference products or of other biosimilars, for reasons of public health.[3] As Johnson & Johnson noted in its Citizen Petition, a distinguishable nonproprietary name scheme is the best approach for ensuring optimal pharmacovigilance and safe use. Distinguishable nonproprietary names will allow for sensitive and faster detection of, and response to, safety signals for a group of related biologics and individual or subsets of products within that group. Distinguishable nonproprietary names also will guard against inadvertent switching of non-interchangeable biologics, which presents unnecessary and avoidable patient risk. And they would limit unintended and unapproved use of biosimilars for indications granted to the reference product but not the biosimilar.

As noted in our Citizen Petition, we support the adoption of distinguishable nonproprietary names for all biologics.[4] We are concerned, however, about FDA's proposal to assign distinguishable suffixes that are "devoid of meaning."[5] A distinguishable suffix will facilitate pharmacovigilance and informed prescribing only to the extent that the healthcare community adopts and correctly uses the suffix. A meaningful—and therefore, memorable—suffix is more likely than a meaningless suffix to achieve FDA's objectives. FDA's proposal to use suffixes derived from license holders' names (e.g., "jnsn" for Janssen) represents one approach to formulating meaningful and memorable suffixes that would enable an effective naming scheme.[6] In addition, a suffix that designates whether the biological product is a reference product or biosimilar would be both meaningful and memorable while also increasing transparency.

The Company also recommends that FDA designate distinguishable suffixes for interchangeable biosimilars and their reference products. Shared suffixes in this context would also create unnecessary and avoidable risks to pharmacovigilance and safe use.

Finally, the agency should provide adequate implementation time for retrospective application of the proposed nonproprietary naming scheme. We recommend that any final version of the Proposed Rule go into effect two years after publication—rather than 90 days after publication, as proposed.[7] An extended implementation period is necessary for this retrospective renaming action to minimize confusion in the marketplace. Healthcare professionals, pharmacists, and patients have years and even decades of experience with the nonproprietary names of the originator biological products identified in the Proposed Rule. The sudden addition of suffixes to these names is likely to be met with surprise and confusion without appropriate education. A two-year implementation period would give FDA and sponsors adequate

---

[3] Johnson & Johnson, Citizen Petition, Docket No. FDA-2014-P-0077-0001 (Jan. 7, 2014) [hereinafter "J&J Citizen Petition"].

[4] *Id.* at 1 n.1.

[5] Draft Guidance, at 10, line 364; 80 Fed. Reg. at 52229.

[6] 80 Fed. Reg. at 52228-29.

[7] *Id.* at 52229.

time to educate healthcare professionals about the forthcoming changes to longstanding nonproprietary names while avoiding undue burdens on industry.

I. FDA Should Require Distinguishable Nonproprietary Names For All Biologics.

Johnson & Johnson supports FDA's proposal to assign distinguishable nonproprietary names for all biological products. As FDA explains in the Federal Register notice announcing the availability of the Draft Guidance, the naming proposal is justified by "a need to clearly identify biological products for the purpose of pharmacovigilance, and, for the purposes of safe use, to clearly differentiate among biological products that have not been determined to be interchangeable."[8] For the following reasons, which are more fully set forth in Johnson & Johnson's Citizen Petition, the Company believes these public health concerns are fully warranted.

First, Johnson & Johnson agrees with FDA that a distinguishable nonproprietary name is a "critical tool" for accurately identifying and facilitating pharmacovigilance. As FDA properly recognizes, while there are other identifiers that could differentiate among biological products, many active (and passive) pharmacovigilance systems have "limited ability" to trace a signal to a specific product when that product shares its nonproprietary name with other products.[9] FDA gives as an example the fact that National Drug Code (NDC) numbers are not routinely recorded in billing and patient records in relevant clinical settings or in adverse event reports.[10] Johnson & Johnson concurs; as we noted in our Citizen Petition, adverse event reporting patterns in the U.S. demonstrate that product name (as opposed to the NDC number) is often the only meaningful product-specific information provided in FDA Adverse Event Reporting System (FAERS) data.[11]

Second, as Johnson & Johnson noted in its Citizen Petition, effective pharmacovigilance is especially critical in the biologics market. Because biosimilars will be approved with limited premarket testing, postmarket surveillance is critical to detecting more subtle product differences, or the clinical significance of those differences, that were not apparent premarket.[12] Pharmacovigilance is also critical to picking up any safety or efficacy concerns or differences that arise over time as the result of intentional or inadvertent manufacturing changes to either the reference product or biosimilar.[13] An inability to effectively trace safety signals to the relevant product can present significant harm to public health. For example, as Johnson & Johnson noted in its Citizen Petition, without proper attribution of adverse events,

---

[8] *Id*. at 52297.

[9] Draft Guidance, at 6, lines 212-18.

[10] *Id*. at 6, lines 218-21.

[11] J&J Citizen Petition, at 6-7.

[12] *Id*. at 5.

[13] *Id*.

safety signals arising from a single product will require a longer time to detect, and it will be difficult to tailor corrective action to the responsible product, resulting in potential disruptions in supply for products that present no safety concern.[14]

Third, Johnson & Johnson agrees that the distinguishable nonproprietary name model is a crucial mechanism for ensuring safe use of biologics.[15] As FDA recognizes, healthcare providers could incorrectly assume that biologics with the same nonproprietary name are interchangeable, based on their experience with small-molecule drugs.[16] In addition, pharmacy substitution practices and physician habits of prescribing by nonproprietary name could lead to unintended substitution in the absence of distinguishable nonproprietary names.[17] Unintended substitution can pose serious and avoidable health risks to patients. As FDA correctly notes, biologics raise "unique safety concerns related to immunogenicity,"[18] and inadvertent switching between non-interchangeable biological products "may affect immune response."[19] Inadvertent substitution could also expose patients to unnecessary risks where a biosimilar is licensed for fewer than all of the indications or routes of administration of the reference product.[20] We agree that distinguishable nonproprietary names "will increase the likelihood that the intended biological product will be prescribed and will not be inadvertently substituted at the dispensing or product administration level."[21]

II. Suffixes Should Be Meaningful and Therefore, Memorable.

The agency should adopt meaningful suffixes for two reasons. First, meaningful suffixes would be more effective in advancing FDA's objectives than suffixes that are "devoid of meaning."[22] Second, meaningful suffixes are unlikely to prompt inaccurate perceptions about biosimilars or hinder their market acceptance. Several approaches to formulating meaningful suffixes are possible, including deriving suffixes from the name of the license holder or developing suffixes that identify the licensing pathway of the product.

In assigning the name "filgrastim-sndz," FDA took the first approach to meaningful and memorable suffixes. Johnson & Johnson would find such an approach acceptable. We appreciate that there are potential downsides to use of license-holder names (e.g., change in license holder, difficulty in harmonizing with other countries),

---

[14] *Id*. at 7.

[15] Draft Guidance, at 5, lines 193-95.

[16] *Id*. at 5, lines 183-84.

[17] J&J Citizen Petition, at 7.

[18] Draft Guidance, at 5, lines 170-80; *see also* J&J Citizen Petition, at 8.

[19] 80 Fed. Reg. at 52226.

[20] Draft Guidance, at 5, lines 172-78.

[21] 80 Fed. Reg. at 52226.

[22] *Id*. at 52228; *see also* Draft Guidance, at 10, line 364.

but believe these are minor in comparison with the risks to adoption and pharmacovigilance were random names used. We note that there are alternative approaches to memorable names that we would also support and would avoid some of these downsides. For example, one might name a product filgrastim-filx, where fil is derived from the "core" name and x represents a distinguishing number or letter indicating approval order (e.g., 1, 2, 3, or a, b, c) or pathway (i.e., new biologic, biosimilar, possibly interchangeability status). Alternatively in this approach, the first three letters could come from the name of the sponsor (e.g., filgrastim-sndx).

A. ***Meaningful Suffixes Will Better Advance FDA's Objectives Than Suffixes That Are Devoid of Meaning.***

In comparison with the suffix convention reflected in the Draft Guidance and Proposed Rule, meaningful suffixes are more likely to facilitate effective pharmacovigilance and safe use.

The meaningful suffixes described are much more likely to be memorable—and therefore, effective for FDA's purposes—than suffixes that purposefully are devoid of meaning. Because providers and pharmacists are more likely to be unable to remember, or liable to misremember, meaningless suffixes, their use could be counterproductive to FDA's pharmacovigilance and safe use goals. In contrast, a meaningful suffix, such as one derived from the sponsor name, is likely to be memorable. Further, adopting one meaningful suffix for all of a license holder's biological products also is simpler than the suffix convention described in the Draft Guidance and Proposed Rule. This approach would not only reduce the administrative burdens associated with the suffix scheme for both FDA and industry, it also would result in a more limited set of suffixes than the Proposed Rule and Draft Guidance. This limitation is likely to make the resulting nonproprietary names easier to remember.

Meaningful suffixes that identify a biologic's licensure pathway would offer several additional benefits. First, these suffixes would provide another cue to identify the product and thus, would promote safe use and pharmacovigilance. For example, where a biosimilar is not approved for all reference product indications, it could be especially important for a prescriber to easily identify the reference product to avoid inadvertent use of the unapproved and unintended product.[23] We expect these situations will become common with time as reference products gain new indications, some of which may be subject to regulatory or patent protection. For instance, after FDA approved ZARXIO™ (filgrastim-sndz), the agency approved its reference product, NEUPOGEN® (filgrastim), for an additional indication that earned orphan drug exclusivity; therefore, ZARXIO is not approved for this indication.[24] Further, as more

[23] If the prescriber recognizes that a product is approved for fewer than all indications of the reference product, the prescriber likely also will already be aware that the product is a biosimilar (or related biological product) in any event.

[24] FDA, sBLA Approval, BLA 103353/S-5183 (Mar. 30, 2015); Database listing for NEUPOGEN, FDA's Database for Orphan Drug Designations and Approvals (last accessed Oct. 20, 2015).

complex biologics with multiple mechanisms of action become reference products, the likelihood increases that a biosimilar product with adequate data to establish biosimilarity in one indication will not necessarily have sufficient evidence of biosimilarity to support approval for another reference product indication.

Second, meaningful suffixes that distinguish products by pathway would promote transparency and facilitate prescriber choice. Prescriber surveys indicate that doctors almost uniformly want to be told when a drug is a biosimilar.[25] For example, according to a recent survey conducted by the Coalition of State Rheumatology Organizations, a nationwide group of state and regional professional rheumatology societies, "[n]early 96 percent of rheumatologists surveyed said the FDA should require labeling to identify a medication as a biosimilar."[26] Providing the identifying mechanism in the nonproprietary name is particularly appropriate if FDA continues its approach to biosimilar labeling thus far. Specifically, the labeling of ZARXIO largely mirrors that of NEUPOGEN and does not disclose that ZARXIO is a biosimilar and not interchangeable with the reference product.[27] Unlike pharmacists, prescribers are unlikely to rely on the *Purple Book* to identify products, making the nonproprietary name the most likely resource they will consult in the absence of transparent labeling. Furthermore, some prescribers and patients may want to use biosimilars specifically because of expected cost savings. Greater transparency in the naming of the product would also facilitate these choices.

B. ***Meaningful Suffixes Are Unlikely to Trigger Inaccurate Perceptions About Biosimilars or Impede Their Market Acceptance.***

Meaningful suffixes—including those identifying the licensure pathway and those derived from the license holder name—are unlikely to trigger concerns that biosimilars are inferior or hinder use of biosimilars.

In the Proposed Rule, FDA asks whether "meaningful suffixes derived from the name of the license holder might create inappropriate market advantages that would impede biosimilar products' acceptance in the market."[28] The agency also expresses concern that a naming scheme that identifies products as biosimilars "could lead to inaccurate and scientifically unfounded assertions of inferiority or clinically meaningful differences."[29] Given the rigorous statutory approval standard for biosimilars, evidence from foreign markets, and public information about the

---

[25] *See, e.g.*, Kevin Olson, ASBM Labeling Survey (Feb. 2015) (survey of 400 physicians showed that 90% of respondents believed that it was important "that a product label for a biosimilar clearly indicates that it is a biosimilar").

[26] Coalition of State Rheumatology Organizations, CSRO Releases Physician Biosimilars Survey Results (2015).

[27] ZARXIO™ Prescribing Information.

[28] 80 Fed. Reg. at 52229.

[29] *Id.* at 52227.

companies who are developing biosimilars, we believe that these concerns are unfounded.

The Biologics Price Competition and Innovation Act of 2009 (BPCIA),[30] which amended the Public Health Service Act (PHSA), authorizes FDA to approve biosimilars only if they are "highly similar" to their reference products "notwithstanding minor differences in clinically inactive components" and have no "clinically meaningful differences" from those reference products in terms of safety, purity, or potency.[31] In light of this demanding statutory standard for biosimilarity, there is no reason to assume that the market would view a suffix as indicating an inherent inferiority of a biosimilar. FDA's *Purple Book* appears to confirm this view, as it identifies currently licensed biologics by licensure pathway—i.e., as reference products, biosimilars, or interchangeable biosimilars.[32]

Furthermore, market experience in Japan casts doubt on the assumption that suffixes identifying licensure pathway would have a material negative effect on market acceptance of biosimilars. Japan's Ministry of Health, Labor and Welfare specifies that a biosimilar's nonproprietary name comprises the nonproprietary name of the reference product with "Biosimilar 1" (or 2, 3, etc.) added as a suffix, and its brand name shall have "BS" added at the end.[33] Despite this practice, it has been reported that particular biosimilars have achieved considerable market acceptance in Japan. For example, Japan Chemical Research Pharmaceuticals' biosimilar erythropoietin product was approved in 2010 with the Japanese Adopted Name of "Epoetin kappa (genetical recombination) [epoetin alfa biosimilar 1]" and with the brand name "Epoetin alfa BS Inj 750/1500/3000 JCR." This product has captured a substantial market share. One article reports that, "[b]y the first quarter of 2014, the biosimilar had achieved a market share of 74% compared to the reference product [Kyowa Hakko Kirin's Espo (epoetin alfa)]."[34]

Designating meaningful suffixes that are derived from license holder names also is unlikely to lead to perceptions that the biosimilars are inferior. As

---

[30] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, Title VII, Subtitle A.

[31] PHSA §§ 351(i)(2), 351(k)(3)(A)(i).

[32] CDER, Center for Drug Evaluation and Research List of Licensed Biological Products with (1) Reference Product Exclusivity and (2) Biosimilarity or Interchangeability Evaluations to Date (updated Oct. 16, 2015).

[33] Japan Ministry of Health, Labor and Welfare, Notice to Directors, Health Bureaus, Prefectural Government on Handling of nonproprietary and brand names of follow-on biologics, PFSB/ELD No. 0304011, (March 2009) (English translation); *see also* Teruhide Yamaguchi, *Quality, Safety and Efficacy of Follow-On Biologics in Japan*, BIOLOGICALS 39(5): 328-332 (2011).

[34] Michelle Derbyshire, *Amgen's move into the biosimilars market*, GABI 3(4): 202-3 (2014); *see also* JCR Pharm. Co., Ltd., Financial Summary: Consolidated Financial Results for Fiscal Year 2013, at 13 (May 9, 2014) (in reporting results for fiscal year 2013, stating, "[a]s to Epoetin Alfa BS Inj. JCR after a five-year marketing effort, the Company successfully increased its share up to 50% or more of short-acting erythropoietin products.").

established manufacturers are planning to market both reference products and biosimilars, a suffix tied to the license holder's name should not connote superiority or inferiority.[35] Indeed, when FDA approved the nonproprietary name "filgrastim-sndz" for the first FDA-approved biosimilar, ZARXIO™, the name was derived from the applicant's name and was proposed by the applicant.[36] In its review decision, furthermore, FDA suggested that the suffix was consistent with the agency's practices for naming biologics and non-promotional.[37]

For the above reasons, Johnson & Johnson believes that meaningful suffixes based on, e.g., license holder name or licensure pathway do not raise market acceptance and uptake concerns.

III. Interchangeable Biosimilars Should Have Distinct Suffixes From Their Reference Products.

Johnson & Johnson believes that the nonproprietary names of interchangeable biosimilars should bear distinct suffixes from the nonproprietary names of their reference products. We favor this approach because it will most effectively achieve FDA's objectives of safe use and optimal pharmacovigilance.

If interchangeable biosimilars and their reference products shared the same suffix, then many pharmacovigilance systems would have difficulty attributing adverse events to the correct product. This is a concern because even a biosimilar that is "interchangeable"—a designation that is presumably granted at one point of time—might "drift" apart from its reference product. That is, either product's structural or quality characteristics might change in clinically meaningful ways after this designation due to intentional or inadvertent manufacturing changes.[38] Either product also might experience contamination or some other substantial quality impairment. Furthermore, rare immunogenic reactions could occur differentially with one product despite an interchangeability showing. In the EPREX/ERYPO case we cited in our Citizen

---

[35] *See, e.g.*, J. Cortes, *Expert Perspectives on Biosimilar Monoclonal Antibodies in Breast Cancer*, BREAST CANCER RES. TREAT. 144(2): 233-39 (2014) (identifying Amgen and Pfizer as having Phase III biosimilar trastuzumab candidates); Press Release, Merck, Merck and Samsung Bioepis Announce Pivotal Phase 3 Studies for Investigational Biosimilars SB4, ENBREL (Etanercept), and SB2, REMICADE (Infliximab), Met Primary Endpoints (June 10, 2015).

[36] FDA, Biological Product Naming Working Group, Memorandum, BLA # 125553, at 3 (March 5, 2015).

[37] *Id.*

[38] The statutory interchangeability provisions do not address the implications of product or manufacturing changes that occur after an interchangeability determination and that could affect substitution and the risk of switching. The BPCIA defines a biosimilar as "interchangeable" with the reference product when the biosimilar "may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product." PHSA § 351(i)(3). To establish interchangeability, an applicant must establish that the product "can be expected to produce the same clinical result as the reference product in any given patient." For products that are administered more than once, the applicant must also meet the requirement that "the risk in terms of safety or diminished efficacy of alternating or switching between" the biosimilar and the reference product must not be "greater than the risk of using the reference product" alone. PHSA § 351(k)(4).

Petition,[39] where a reformulation resulted in an increased number of reports of erythropoietin antibody-mediated pure red cell aplasia in certain patients, it would have been difficult for the Company to identify the safety signal had there been multiple interchangeable erythropoietin products with the same nonproprietary name on the market. Increases in group-wide adverse event incidence rates tend to be more modest than product-specific safety signals and more likely to be attributed to random chance. Even if the safety signal had been associated with erythropoietin products as a class, delay or impairment of the ability to isolate the safety signal to a particular product might have required regulatory authorities to take remedial action against the entire class to the detriment of patient care.

In addition to pharmacovigilance concerns, having shared nonproprietary names for interchangeable biosimilars and their reference products could also negatively affect safe use. We infer from FDA indicating that an interchangeable biosimilar might have the same suffix as its reference product that FDA will expect interchangeable biosimilars to be approved for all reference product indications; otherwise, the agency's safe use concern applies equally to interchangeable biosimilars and supports distinct suffixes. In any case, even if FDA determined that an interchangeable product may only be approved for all indications of the reference product, the reference product could acquire additional indications after the interchangeability designation. In such cases, patients may unintentionally be placed on, or switched to, a product that has not been approved for the patients' condition due to confusion stemming from the reference product and interchangeable biosimilar sharing the same nonproprietary name. Such unintended substitution creates an unnecessary risk of harm, which could be avoided if interchangeable biosimilars had distinguishable suffixes from their reference products. Moreover, lacking guidance on interchangeability, it is not clear the extent to which the agency will permit slight variations in instructions for use for interchangeable biosimilars. Shared suffixes for products with different instructions for use could result in additional problems for safe use.

Furthermore, FDA has not indicated whether products that are deemed interchangeable with the reference product will be assessed for interchangeability with one another. If FDA does not require interchangeable biosimilars to be proven interchangeable with each other, and if the standards and experience do not support an assumption that they are interchangeable, shared nonproprietary names present risk of unintended switching between, and pooling of adverse events for, these non-interchangeable products.

Finally, it is not necessary for the reference product and interchangeable biosimilar to share nonproprietary names for substitution to occur. FDA's *Purple Book* will indicate if a biosimilar has been designated interchangeable, and pharmacists may use it to guide substitution of interchangeable biosimilars as they do with the *Orange Book* for small molecules.

[39] J&J Citizen Petition, at 4.

IV. FDA Should Provide A Reasonable Implementation Period for Retrospective Application.

FDA has proposed that a final rule based on the Proposed Rule would become effective 90 days after its publication.[40] Given the complexities and potential for confusion associated with retrospective name changes, Johnson & Johnson recommends that FDA instead provide an implementation period of two years from the issuance of the final rule. This period would allow license holders and FDA to educate healthcare professionals, pharmacists, and patients on the name change to minimize anticipated market confusion and also avoid undue burdens for sponsors.

The agency has recognized that confusion is likely when the longstanding nonproprietary name of a medicine changes. For instance, FDA emphasized this point in denying a citizen petition filed by Winston Laboratories. The petition requested that FDA designate an official name for a drug that differed from its United States Adopted Name (USAN), zucapsaicin.[41] Winston's request was based on its concern that this USAN had potential for confusion with "capsaicin" that could lead to medication errors.[42] FDA rejected Winston's request, stating: "Changing a nonproprietary name in usage worldwide for more than a decade would likely contribute to, not resolve, any confusion within the scientific and medical communities."[43] The current renaming proposal shares features with this situation. For instance, "infliximab" is a USAN that has been used in the U.S. to refer to a licensed biologic since 1998. Therefore, a material risk of confusion exists from changing this nonproprietary name. Without appropriate education, healthcare professionals, pharmacists, and patients might misinterpret the addition of a suffix to a nonproprietary name to mean that the product has changed or that it is a new product rather than the one they have successfully prescribed, dispensed, and used for years.

As a result of this confusion, existing patients who are stable on the reference product might be inadvertently switched to an approved biosimilar, while new patients might be placed on an unintended drug that may not be approved for the intended use. Further, inadvertent substitution could lead to substantial patient harm, including, as FDA noted in its preamble, "unique safety concerns related to immunogenicity."[44]

Therefore, to avoid the potential risk to patient harm from inadvertent substitution, FDA should provide for a reasonable implementation period that would

---

[40] 80 Fed. Reg. at 52229.

[41] Winston Labs., Inc., Citizen Petition, Docket No. 2004P-0265 (now Docket No. FDA-2004-P-0472) (May 24, 2004).

[42] *Id.* at 2.

[43] FDA, Response to Winston Laboratories' Citizen Petition, Docket No. 2004P-0265 (now Docket No. FDA-2004-P-0472) (Sept. 8, 2005), at 10.

[44] 80 Fed. Reg. at 52226.

allow license holders and FDA to provide necessary education on the name change to healthcare professionals, pharmacists, and patients before its rollout. If these individuals are expecting the name change and understand what it means—including that the product they have used for years has not changed—the risks associated with the name change will be appropriately mitigated. Ninety days is an inadequate time period to carry out this necessary education, but two years should be sufficient.

* * *

Johnson & Johnson appreciates FDA's thoughtful consideration of the optimal nonproprietary naming system for biologics and would welcome the opportunity to discuss these comments further.

Sincerely,

JAY SIEGEL

Digitally signed by JAY SIEGEL
DN: c=US, o=JNJ, ou=Employees, ou=196030, cn=JAY SIEGEL, email=JSiegel2@its.jnj.com
Reason: I attest to the accuracy and integrity of this document.
Date: 2015.10.27 15:38:06 -04'00'

Jay P. Siegel, MD
Chief Biotechnology Officer and Head,
Scientific Strategy and Policy
Johnson & Johnson