

Comment of the Staff of the Federal Trade Commission¹

Submitted to the Food and Drug Administration
Department of Health and Human Services

In Response to a Request for Comments on FDA’s Guidance for Industry on the
“Nonproprietary Naming of Biological Products; Draft Guidance for Industry; Update”

[Docket No. FDA-2013-D-1543]

84 Fed Reg. 8534 (Mar. 8, 2019)

Submitted on May 6, 2019

The staff of the Federal Trade Commission’s Office of Policy Planning, Bureau of Economics, and Bureau of Competition (“FTC staff”) appreciates the opportunity to respond to the Food and Drug Administration’s (“FDA”) Request for Comments on its *Updated Guidance for Industry: Nonproprietary Naming of Biological Products [hereinafter 2019 Updated Guidance]*.² In this draft guidance, the FDA proposes: (i) to add a distinguishable suffix **only** to the nonproprietary name of each biosimilar and interchangeable product; but (ii) not to retroactively provide four-letter suffixes to the names of any reference biologic products approved before January 2017.

This Comment is a brief addendum to two previous comments filed by the FTC: (i) a public comment filed in 2018 with the Department of Health and Human Services (“HHS”); and (ii) a public comment filed in 2015 with the FDA. Both comments

¹ This Comment represents the views of the Federal Trade Commission’s Office of Policy Planning, Bureau of Economics, and Bureau of Competition. This comment does not necessarily reflect the views of the Commission or any individual Commissioner. The Commission has voted to authorize the staff to submit this comment.

² Notice of Nonproprietary Naming of Biological Products: Update; Draft Guidance for Industry; Availability, 84 Fed. Reg. 8534 (proposed Mar. 8, 2019) (to be codified at 21 C.F.R. 10.115) [hereinafter 2019 Notice], <https://www.federalregister.gov/2019/03/08/>.

expressed our concern that the disparate treatment and the differentiated naming of biosimilar products would reduce biosimilar competition in the United States.³

The FDA has issued three naming guidance documents for biosimilar products: (i) the first in 2015;⁴ (ii) the second in 2017;⁵ and (iii) the third and subject of this Comment—the *2019 Updated Guidance*.⁶ The two earlier guidance documents recommended including a distinguishing but otherwise meaningless suffix on the names of biologic products, including biosimilar products. This prior guidance departed from the FDA’s traditional naming protocol for nonproprietary drugs.

In our previous comments, we raised a concern that the FDA’s proposed naming protocol would diminish the use of biosimilar and interchangeable products.⁷ We noted that the use of these meaningless suffixes might limit entry of new competitors (or weaken competition from new entrants) because new competitors would incur additional

³ See Fed. Trade Comm’n, *Staff Comment to FDA on Draft Guidance for Industry on the Nonproprietary Naming of Biological Products* (Oct. 27, 2015) [hereinafter 2015 FTC Naming Comment], <https://www.ftc.gov/ftc-staff-comment-submitted/151028fdabiosimilar.pdf>; Fed. Trade Comm’n, *Statement of the Federal Trade Commission to the Department of Health and Human Services Regarding the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs* (July 17, 2018) [hereinafter 2018 FTC Blueprint Comment], <https://www.ftc.gov/policy/advocacy/advocacy-filings/2018/07/statement-federal-trade-commission-department-health-human>. For a fuller discussion of our concerns, see 2018 FTC Blueprint Comment at 8-19, appended hereto.

⁴ Notice of Nonproprietary Naming of Biological Products: Draft Guidance for Industry; Availability, 80 Fed. Reg. 52,296 (Aug. 28, 2015) [hereinafter 2015 Draft Guidance], <https://federalregister.gov/a/2015-21383>. The FDA sought comment on whether the nonproprietary name for an interchangeable product should include a unique, distinguishing suffix, or should share the same suffix as its reference product. The FDA also asked whether the suffix should be meaningful or devoid of meaning, and what effect each naming option would have on the safe use, pharmacovigilance, market acceptance and uptake of biological products. See 2015 Draft Guidance at 52,297.

⁵ Notice of Nonproprietary Naming of Biological Products: Draft Guidance for Industry; Availability, 82 Fed. Reg. 4345 (Jan. 13, 2017), <https://www.govinfo.gov/content/pkg/FR-2017-01-13/pdf/2017-00694.pdf>.

⁶ 2019 Notice, *supra* note 2, at 8534.

⁷ See 2015 FTC Naming Comment, *supra* note 3; 2018 FTC Blueprint Comment, *supra* note 3, at 14-18.

costs to overcome any (mis)perception of quality difference and substitutability for biosimilar products that might be implied by the naming convention. In particular, we raised four points:

1. the FDA's decision to assign different suffixes to the drug substance names of biosimilars and their reference biologics could result in physicians incorrectly believing that biosimilars' drug substances differ in clinically meaningful ways from their reference biologics' drug substances;
2. biosimilars with distinct nonproprietary names are less commercially successful than biosimilars with the same nonproprietary name as the reference biologic;
3. reliance on trade names would address the FDA's pharmacovigilance concerns and address the FDA's concerns with unintended switching of products not determined by the FDA to be interchangeable; and
4. the FDA could require unique brand names for all biologics, while preserving the same active ingredient name across all therapeutically substitutable products in the same biologic category.⁸

The FDA's *2019 Updated Guidance* raises additional concerns: it recommends the use of the distinguishing but otherwise meaningless suffixes, but only for: (i) the nonproprietary names of reference biologic products that the FDA approved after January 2017; and (ii) all biosimilar and interchangeable products.⁹ This would create two

⁸ See 2018 FTC Blueprint Comment, *supra* note 3, at 15-17.

⁹ See 2019 Notice, *supra* note 2, at 8534. The FDA has proposed to exempt certain biologics from the *2019 Updated Guidance*. These are called transition products, and the 2019 Updated Guidance would not apply suffixes to transition products. Transition products consist of such products as insulin and human growth hormone. These fall under the "Deemed to be a License" provision in in §7002(e) of the Biologics Price Competition and Innovation Act ("BPCIA"). See Food & Drug Admin. Guidance, *Interpretation of the*

classes of biological products: (1) those with nonproprietary names that *do not have* a suffix—namely, reference biologics approved before 2017; and (2) those *with* a suffix, offered by new entrants. This unusual naming convention—applied exclusively to a subset of new entrants—likely would create consumer confusion and discourage use of newly introduced biosimilar and interchangeable products.¹⁰ Inconsistency of naming practices may thus diminish future competition.¹¹

As we suggested in our earlier comments,¹² the FDA has recognized that the retrospective application of the 2017 Naming Guidance to all reference biologic products would be too complicated, confusing, and costly to implement.¹³ This would be as true for the application of the conventions of the *2019 Updated Guidance* as it was for the 2017 Naming Guidance.

For these reasons, we recommend that the FDA abandon the use of these suffix-based naming proposals.

“Deemed to be a License” Provision of the BPCIA of 2009, <https://www.fda.gov/Guidances/UCM490264.pdf>. FDA determined retroactively applying suffixes to these transition biologic products would be too confusing and burdensome. See 2019 Notice, *supra* note 2, at 8534.

¹⁰ See David Wallace, *IGBA Still Sees a Path to Change FDA’s Mind on Biological Suffixes* GENERICS BULLETIN (Apr. 3, 2019), <https://generics.pharmaintelligence.informa.com/GB140215/IGBA-Still-Sees-A-Path-To-Change-FDAs-Mind-On-Biologic-Suffixes?vid=Pharma>.

¹¹ The inconsistent and differential naming convention of the *2019 Updated Guidance* also may undercut the pharmacovigilance purpose of suffixes. A failure to use the appropriate suffix in an adverse event report is on its face ambiguous, and thus may result in misattribution of an adverse event to the wrong product.

¹² See 2015 FTC Naming Comment, *supra* note 3; 2018 FTC Blueprint Comment, *supra* note 3, at 14-18.

¹³ See 2019 Notice, *supra* note 2, at 8345.

As the Commission expressed in its prior comments, market penetration of biosimilars in the United States lags behind biosimilar penetration and price competition in Europe.¹⁴ As of April 28, 2019, FDA has approved 19 biosimilars to nine reference biologics, but only eight are commercially available, the rest are held up by patent issues.¹⁵ In contrast, as of April 2019, the European authorities have approved 53 biosimilars, all of which are commercially available and have generated savings in the tens of billions of dollars.¹⁶ The FDA can foster biosimilar competition in the United States, including adopting naming conventions that do not discourage the use of these lower cost alternatives.

We appreciate this opportunity to provide our views on the *2019 Updated Guidance*. We support the efforts by HHS and FDA to examine ways to increase competition in health care markets and look forward to continuing our work with both agencies on this issue.

¹⁴ See 2018 FTC Blueprint Comment, *supra* note 3, at 11-12 (noting greater discounts in Europe (over 75% discounts on 43 products) compared to the US (15-45% discounts on three products)).

¹⁵ FOOD & DRUG ADMIN., *Biosimilar Product Information*, <https://www.fda.gov/drugs/biosimilar-product-information>; Michael Cipriano & Bridget Silverman, *Keeping Track: A Glut of Big Approval While Lartruvo Makes Its Market Exit*, PINK SHEET (Apr. 28, 2019), <https://pink.pharmaintelligence.informa.com/> (“FDA has approved 19 biosimilars overall, although only a handful have launched due to patent litigation.”); *Diagnosing the Problem: Exploring the Effects of Consolidation and Anticompetitive Conduct in Health Care Markets*, Hearing Before the H. Judiciary Comm, Subcomm. on Regulatory Reform, Commercial and Antitrust Law, 116th Cong. 5-7 (2019) (statement of Dr. Fiona Scott Morton) (citing Ronny Gal, *Biosimilars: Adoption Update in EU & US - Dec '18 Data*, BERNSTEIN GLOBAL SPECIALTY PHARMA & US BIOTECH (Feb. 26, 2019)) <https://docs.house.gov/meetings/HHRG-116-JU05-Wstate-MortonF-20190307.pdf>; Zachary Brennan, *FDA Approves 19th Biosimilar, 2nd for Enbrel*, RAPS (Apr. 26, 2019), <https://www.raps.org/news-and-articles/news-articles/2019/4/fda-approves-19th-biosimilar-2nd-for-enbrel>.

¹⁶ ADVANCING BIOSIMILARITY SUSTAINABILITY IN EUROPE: A STAKEHOLDER ASSESSMENT, IQVIA (Sept. 2018), <https://www.iqvia.com/institute/reports/advancing-biosimilar-sustainability-in-europe>.