February 7, 2017

Office of Information and Regulatory Affairs
Office of Management and Budget
Attn: FDA Desk Officer
oira_submission@omb.eop.gov

Re: OMB Control No. 0910-New, "Nonproprietary Naming of Biological Products"
Docket No. FDA-2013-D-1543

Dear FDA Desk Officer:

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit American National Standards Institute (ANSI)-accredited Standards Development Organization (SDO) consisting of nearly 1600 members who represent drug manufacturers, chain and independent pharmacies, drug wholesalers, insurers, mail order prescription drug companies, claims processors, pharmacy benefit managers, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, industry professional societies, service organizations, government agencies, and other parties interested in electronic standardization within the pharmacy services sector of the healthcare industry.

On behalf of NCPDP, we wish to express grave concerns regarding the enormous financial consequences of the FDA's proposal for renaming all biological drugs described in the Agency's January 2017 Guidance "Nonproprietary Naming of Biological Products." NCPDP is already on record with the FDA regarding patient safety and other concerns. (Please see attached letters to FDA from August 20, 2012 and October 27, 2015). While the FDA believes the core name + Suffix will be inserted into the International Nonproprietary Name (INN) slot with no cost to the healthcare industry except for the sponsors, this ignores the impact of the wide spread downstream usage of the INN.

The FDA mandate to rename every biological drug, including drugs that have been marketed for years under a different nonproprietary name, will require every segment of healthcare including, but not limited to, hospitals, payer, and providers to engage in thousands of hours of information technology redesign and reprogramming. In addition to the considerable impact on the private sector, the impacted government entities would include Veterans Health Administration, Ryan White Centers, Indian Health Service, Centers for Medicare and Medicaid Services, Department of Defense, National Institutes of Health, and all other Federal, state, and local government health agencies. We are confident the initial direct implementation costs will be in the billions of dollars. We also anticipate extensive on-going indirect costs associated with drug price increases, adverse patient safety issues, drug shortages, and supply chain disruption.

The fundamental omission in the FDA's perspective arises from an incomplete awareness of the comprehensive electronic programming that underlies the prescribing and dispensing of drugs in the United States, due in large part to federal efforts to promote healthcare information technology. In this environment, all drugs are categorized by ingredient (generally using the INN), and the resulting categories are employed in computer coding on which drug ordering, clinical review and claims

administration are dependent. Individual drug names and NDCs are not routed through these systems, but classes of products with the same ingredient, route of administration, dosage form and strength serve as the primary inputs in algorithms that determine a broad scope of multiple, long-established workflows. Any change to a product name requires any associated programming based on name to also change, to an extent that has not been recognized and in fact has been ignored in the naming Guidance.

As an illustration of the necessary scope of work when the renaming of biological drugs commences, we would note the following comments:

Erin Fox, PharmD, FASHP, Director, Drug Information Service, University of Utah Health Care

> *"At their staff meeting, our pharmacy informatics pharmacists discussed the issue of the new nonsense suffix being added to biologic products and the additional workload….They believe that a reasonable estimate is about 40 hours* ***per product*** *which would include impacts on ERX in Epic, labels, scanning, billing, changing order sets, changing smart pumps, pharmacy automation, automated dispensing cabinets, etc….It will be nearly impossible to use up all of the "old" product without the nonsense suffix and then switch out to the new product with the nonsense suffix. The pharmacy will have to bear the cost of the unusable "old" product because the system can't handle a mixed inventory for the same item. Will hospitals have to redo contracts for these products? There is probably 2 – 10 hours of time per contract for pharmacy to review, legal to review, and then back and forth to get things signed....So…. 50 – 70 hours per product plus the cost of old product when switching. Then there are potential unforeseen costs due to unintended consequences that will increase prices."*

Patrick Lupinetti, Senior Vice-President, First Databank, Inc.

> *"Every name change involves a drug classification change, for compendia and RxNorm, and the consistent representation we have heard from our hospital customers – as they urge that all such changes be minimized – is that each such instance implicates as much as 50 hours of programming per drug."*

Applied against the number of BLA-holding products in the market – DailyMed lists nearly 15,000 NDCs – these workload estimates demonstrate the impact that implementation of the proposed policy will have. Granting that a given facility will not be using all these products, even a thousand multiplied by 50 hours per drug and a reasonable labor cost per hour will occasion tens of thousands of hours in reprioritized work efforts and millions of dollars in added cost for a single entity. With 5,500 hospitals in the U.S., more than 60,000 pharmacies, and a host of pharmacy benefit managers, physician practices, group purchasing organizations, wholesalers and pharmaceutical manufacturers, the total price tag for implementation of the proposed naming convention is staggering.

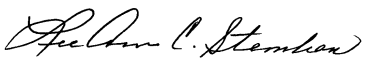
NCPDP consequently urges the Office of Management and Budget to suspend further implementation of the policy outlined in the above-captioned guidance until its resulting costs have been fully identified, analyzed and addressed. NCPDP will participate in any review process relating to this matter and provide any information and assistance that may be required.

Thank you for your consideration of these concerns. For direct inquiries or questions related to this letter, please contact:

Terry Fortin

Standards Specialist, NCPDP
Direct: 480-297-4593
tfortin@ncpdp.org

Sincerely,



Lee Ann C. Stember
President
National Council for Prescription Drug Programs (NCPDP)
9240 E. Raintree Drive
Scottsdale, AZ 85260