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First Databank

February 10, 2017

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

Office of Information and Regulatory Affairs
Office of Management and Budget
Attn: FDA Desk Officer

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

Dear FDA Desk Officer:

On behalf of FDB (First Databank, Inc.), 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." As we and others noted in previous meetings and communications with the FDA, applying the proposed naming procedure, even if limited only to newly approved biosimilar drugs, was an example of a solution going in search of a problem. It is clear that there are numerous and preferable ways to identify the manufacturer of a biosimilar without causing the confusion that addition of a hyphen and four-character suffix will create. We emphasized that introducing an entirely new, untested method of naming these new drugs would create foreseeable patient safety risks and was frankly unnecessary.

However, given the expansion of the scope of the naming proposal described in the Guidance, we write to stress the huge and unappreciated financial effect that not only naming newly approved biosimilar drugs, but *renaming all previously approved biological products*, will create. The Guidance suggests that the new naming structure – a core ingredient name plus a meaningless four-letter suffix – can be substituted for a drug's existing United States Adopted Name (USAN) (which traditionally corresponds to the International Nonproprietary Name (INN) ) with minimal cost to the healthcare industry beyond the sponsoring manufacturers. However, this fails to take into account the impact of the wide spread downstream usage of the USAN/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

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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.

We believe that there is a fundamental omission in the FDA's perspective, one that 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 (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.

While effecting a name change is not a process that involves technical or operational difficulties for publishing compendia such as FDB, we are acutely aware of the problems it causes for our customers. Since every name change involves a drug classification change for all electronic compendia including the National Library of Medicine's RxNorm, 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 name change.

Applied against the number of BLA-holding products in the market – DailyMed lists nearly 15,000 NDCs – this workload estimate demonstrates 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 biological drug name changes multiplied by 50 hours per drug and a reasonable labor cost per hour will occasion millions 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.

FDB 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.

Thank you for your consideration of these concerns.

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