

June 6, 2014

Margaret A. Hamburg, MD
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Meeting held 1st May 2014 to discuss Nonproprietary Naming of Biologics

Dear Dr. Hamburg:

The National Council for Prescription Drug Programs (NCPDP) would like to thank the FDA for meeting to discuss the nonproprietary naming of biologics, and in particular, our concerns with the non-traditional nomenclature recently applied by the Agency to ado-trastuzumab emtansine and tbo-filgrastim. We greatly appreciate the time and attention that were given to our concerns and your interest in continuing to work with us. NCPDP and our member stakeholders will continue to collaborate with the FDA to ensure that the data made available to downstream users, including physicians, pharmacists, and patients, are not only accurate, but also the most informative and least confusing they can be. By working together to maintain a high integrity, unambiguous standards-driven system, we can reinforce existing naming standards designed to support the safe and effective use of all medicines in the interests of all stakeholders, but most especially patients.

As we indicated, NCPDP is a not-for-profit ANSI-accredited Standards Development Organization (SDO) consisting of more than 1,500 members who represent drug manufacturers, chain and independent pharmacies, drug wholesalers, insurers, mail order prescription drug companies, pharmaceutical claims processors, pharmacy benefit managers, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies, professional societies, and other parties interested in electronic standardization within the pharmacy services sector of the healthcare industry. NCPDP provides a forum wherein our diverse membership can develop solutions, including ANSI-accredited standards, and guidance for promoting information exchanges related to medications, supplies, and services within the healthcare system

Critically important to these activities is ensuring broad-based adoption of widely recognized and accepted standardized naming and coding practices for a wide array of data attributes about medications, including nonproprietary naming conventions. As discussed in our meeting with FDA staff, unambiguous, interoperable, meaningful data exchange is jeopardized anytime standard operating procedures (SOPs) are violated in these naming and coding practices. Unintended, potentially serious consequences can result.

During the meeting, we showed how the drug compendia compile data and make them available to various stakeholders who then create the interface for their own specific downstream needs – whether that is in retail pharmacy, hospital, or other healthcare settings. While the compendia can accommodate most data needs, we caution that in making changes to the current databases and the SOP's by which they are developed, maintained, and used takes time and resources. This can result in confusion, errors, and misunderstanding, resulting in a very real risk to patients, during any transition. The compendia groupings are used as the basis for a variety of outcomes many of which will be disrupted if standard nonproprietary naming conventions for determining acceptable “established names” are violated. Each process will have to be individually rebuilt to ensure patient safety and restore functionality to the system. While that can be done, there is a danger in disruption. For your convenience, we have attached the

slides that we presented at our meeting and encourage you to make them available to others who were unable to attend, and likewise the other handouts of those biologics currently marketed in the US that share nonproprietary names without any safety concerns.

We also have attached a slide (3. Marketplace Solution) summarizing the level of required data elements associated with any prescription drug transaction as just one indication of the type of product-specific detail that currently is being tracked via NCPDP's Telecommunication Standard. This existing marketplace solution provides a far superior method for supporting prescription tracking and pharmacovigilance activities than would any proposed need for nonproprietary naming distinctions.

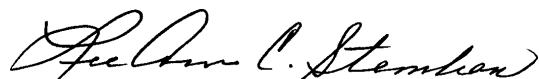
NCPDP also agrees with the FDA that it is critical to address accuracy and record keeping, but cautions against an expectation that changes to the current systems can ever compensate for the failure to maintain complete and accurate records. We would like to help you avoid the problems created in the ado-trastuzumab emtansine/ trastuzumab emtansine situation where even after a year's time, FDA, the National Library of Medicine (NLM), National Cancer Institute (NCI), United States Pharmacopeial Convention (USP), United States Adopted Names (USAN) Council, and others have inconsistent nomenclature in use. We would anticipate similar challenges with tbo-filgrastim/filgrastim and any other situation where the ingredient is given a different name. Any difference however big or small is a difference that will impact how data are pooled, sorted, and transferred unambiguously.

NCPDP has years of experience in observing how small, seemingly inconsequential, changes in product descriptions and data formatting or structure can have significant consequences within healthcare. We need your help to understand the changes that you think could be necessary to current systems, and are very willing to work with you to evaluate more fully any ideas you may have. We may also be able to suggest alternative ways to address your concerns and can provide advice on the safest ways to implement any new requirements to maximize their effectiveness and ensure a safe transition

NCPDP is available to work with you. Through a consensus building process in collaboration with other industry organizations, our members develop solutions to improve safety, privacy, and healthcare outcomes for patients and healthcare consumers, while reducing costs in the system. NCPDP has over thirty-five years of commitment to furthering the electronic exchange of information about medications among healthcare stakeholders.

NCPDP looks forward to working with the FDA to establish practical but standardized ways to ensure the safety and proper product identification of medications.

Respectfully,



Lee Ann C. Stember
President
NCPDP

Attachments:

1. Presentation to FDA May 1, 2014



20140501NCPDP deck
for FDA.pptx

2. Biosimilar by Name and Biosimilar by Nature Article (May 1, 2014 meeting handout)



Biosimilar by Name
and by Nature Article.

3. Marketplace Solution



Marketplace Solution
25.pdf

NCPDP WG2 Product Identification Co-Chairs
Anne Johnston, Express Scripts
Reem Mohamed, First DataBank
Kay Morgan, Gold Standard

For direct inquiries or questions related to this letter, please contact

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FDA Meeting invitees and attendees

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Robert Ball, MD, MPH, Deputy Director, Office of Surveillance and Epidemiology, CDER
Sandra Benton, Senior Policy Analyst, Office of Medical Policy, CDER
Leah Christl, Ph.D., Associate Director for Therapeutic Biologics, OND Therapeutic Biologics and Biosimilars Team (TBBT), OND, CDER
Christopher C. Joneckis, PhD, Senior Advisor for Chemistry, Manufacturing, & Control, CBER
Steven Kozlowski, MD, Director, Office of Biotechnology Products, OPS, CDER
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