Specialty Pharmacy Solutions - **Client Alert** - 09/23/2016

United Health Dumps Neupogen in Favor of Zarxio -- in Spite of NO 'Interchangeability' designation ©

Before we get to the main part of this Alert let me point to the FDA press release below detailing its ongoing (*snail paced*) process of finalizing biosimilar regulations….. especially related to the highly prized designation of "interchangeability". As noted in the press release, FDA has pushed back that thorny issue to beyond December 2017. In the meantime a new unofficial designation is being substituted….. "highly similar". *I am clueless to understand where that term came from. It is like saying someone is "almost pregnant".*

Now here is where it gets interesting……
This week United Health announced it will exclude Amgen's white blood cell-boosting drug Neupogen from coverage starting in 2017 in favor of Zarxio, the biosimilar sold by Novartis. Zarxio, as you should recall, was approved with the generic name of "filgrastim-**sndz**". And you should also be now familiar that the suffix (-sndz) means that the FDA decided to approve the new drug, but not as a fully A/B rated interchangeable product.

United must be comfortable with the "highly similar" designation to totally drop the reference product (Neupogen) from its formulary. We believe it is the first instance where a large insurer / PBM has taken that hard a line. (*Let us know if you are aware of other similar instances.*)

What is perhaps most bewildering is why Amgen was unsuccessful in keeping Neupogen on United's formulary. We have previously predicted that reference product manufacturers, in this case Amgen with a mountain of cash, could simply offer a big rebate for Neupogen to stay on formulary. Could there have been a behind the scenes 'rebate battle to the death' between Amgen and Novartis….. and Amgen lost? *Would like to have been a fly on the wall listening in on what really led to dumping Neupogen*.

# # # # # # # # # #

FDA To Push Back Release of Biosimilar Interchangeability Draft Guidance

22 September 2016 ---Although the Food and Drug Administration (FDA) has continued to say publicly that draft guidance on how an interchangeable biosimilar will be defined should come out by the end of 2016, the user fee reauthorization commitment letter released this week says the draft will publish sometime before 31 December 2017.

The letter, which contains the performance goals and procedures for the Biosimilar Biological Product User Fee Act (BsUFA) reauthorization for fiscal years 2018-2022 (known as BsUFA II), also said that FDA will work toward the goal of publishing a revised draft or final guidance on interchangeability within two years after the close of the public comment period of the draft, meaning the final interchangeability guidance may not take effect before 2019.

FDA also sets the same 31 December 2017 deadline for draft guidance describing statistical considerations for the analysis of analytic similarity data intended to support a demonstration of "highly similar" for biosimilars, and says it will work toward the goal of publishing a revised draft or final guidance within 18 months after the close of that public comment period.

Other Guidance

In terms of other guidance for biosimilar developers, the agency noted that on or before 31 March 2019, FDA will publish draft guidance describing processes and further considerations related to post-approval manufacturing changes for biosimilars. FDA will also publish revised draft guidance on

- "Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants" no later than 30 September 2018, and it will update the current draft or final guidance on
- "Best Practices for Communication Between IND Sponsors and FDA During Drug Development," to apply to communications between IND sponsors and FDA during biosimilar development by 31 December 2018.In addition, FDA will work towards the goal of publishing revised draft guidance or final guidance documents on or before 31 May 2019 for draft guidance published between 2014 and 30 September, including: Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product (draft guidance published in May 2014) Nonproprietary Naming of Biological Products (draft guidance published in August 2015) Labeling for Biosimilar Biological Products (draft guidance published in March 2016)

Goals
As far as biosimilar review performance goals under the next BsUFA, for original 351(k) biologics license application (BLA) submissions, the BsUFA review clock will begin at the conclusion of the 60 calendar day filing review period that begins on the date of FDA receipt of the original submission. FDA plans to review and act on 90% of original 351(k) BLA submissions within 10 months of the 60-day filing date.

In terms of Biosimilar Biological Product Development (BPD) meeting requests, FDA will notify the requester in writing of the date, time and place for the meeting, as well as expected Center participants following receipt of a formal meeting request and background package. FDA says it will respond to meeting requests and provide notification within 21 calendar days for initial advisory meetings, 14 calendar days for BPD Type 1 meetings and 21 calendar days for Type 2-4 meetings.

For Biosimilar Initial Advisory and BPD Type 2 meetings, FDA says the sponsor may request a written response rather than a face-to-face meeting, videoconference or teleconference, and if deemed appropriate, FDA will notify the requester of the date it intends to send the written response. In terms of meeting scheduling or written responses, Biosimilar Initial Advisory requests will be responded to in 75 calendar days from receipt of meeting request and background package and for BPD 2 meetings it will be 90 calendar days. And in terms of scheduling a time for a meeting, for BPD 1 meetings, FDA will offer a response in 30 calendar days from receipt of meeting request and background package, a response to BPD 3 requests in 120 calendar days and within 60 calendar days from receipt of meeting request and background package of BPD 4 requests.

BIOSIMILAR BIOLOGICAL PRODUCT REAUTHORIZATION PERFORMANCE GOALS AND PROCEDURES FISCAL YEARS 2018 THROUGH 2022 - See more at: http://www.raps.org/Regulatory-Focus/News/2016/09/22/25885/FDA-May-Push-Back-Release-of-Biosimilar-Interchangeability-Draft-Guidance/#sthash.cUwHY9Ly.dpuf

****

****

Sully
Bill Sullivan

Principal Consultant
Specialty Pharmacy Solutions LLC
Phone: 781-929-4302
Fax: 781-394-7781

Total Specialty Rx Solutions