Good afternoon, Karen

Thank you for the reminder and below are comments for your consideration. I wanted to take a moment and thank you and the team again for allowing me to be part of this process. I look forward to our next meeting.

- **836-200-0505(4) "Inaccurate or Incomplete Information" Definition**
    - "All available information" seems very expansive.
    - What if a mistake was made to the information inadvertently? "False or misleading" does not seem to encompass that situation.
- **836-200-0505(6) "New Prescription Drug" Definition**
    - (b) It seems as though there should be more clarity on what "continuously marketed" means. What if the product was pulled from the market and not end-dated with the FDA? How will "continuously marketed" be determined?
    - Where do authorized generics fall under this definition? Are they being excluded from the definition?
- **836-200-0505(11) "Reporting Manufacturer" Definition**
    - The definition for a reporting manufacturer requires that all of the listed criteria must be met, however, a virtual manufacturer does not seem to meet the criterion outlined in (b) as they do not engage in the manufacture of prescription drugs in accordance with the definition provided under ORS 646A.689(1)(d). Are virtual manufacturers intended to be included? It would appear that way due to the language in (c). It seems as though this definition needs more clarity on virtual manufacturers and whether or not they qualify as reporting manufacturers.
- **836-200-0510(1) Account Generation Requirement**
    - Wouldn't 10 days prior to a required reporting deadline always be sooner than 30 days after becoming a reporting manufacturer? A company only becomes a reporting manufacturer after it has begun having sales in Oregon and the new drug report is due 30 days after introduction of a new prescription drug for sale in the U.S.

Have a great weekend,

Lynetta

Lynetta Moore (she/her)

Director, BPaaS