GRIFFITH Numi L * DCBS

From: Judy Fox <Judy.Fox@qpharmacorp.com>
Sent: Tuesday, January 18, 2022 3:08 PM
To: GRIFFITH Numi L * DCBS; WINKEL Karen J * DCBS; GRIFFITH Numi L * DCBS; SOUCY Cassandra * DCBS; GARBER Haven * DCBS; BOONE Christina M * DCBS; JOSHI Elaine * DCBS; OBRIEN Jesse E * DCBS
Cc: Judy Fox
Subject: FDA response to assigning a value to drug samples

Good Afternoon All,

As a follow up to the discussions on today's call regarding assigning a value to drug samples, I did reach out to the FDA directly in the fall to ask if assigning a value would be a violation of the Prescription Drug Marketing Act (PDMA) 21 CFR part 203.
I was not sure if you received the email below, but the FDA's response is in the email trail below where they actually agree with assigning a value, but distinguishing that from samples having a price. The office of Compliance was cc'd on the response I received and there has not been any communication from that office indicating that they had an issue with the opinion presented to me in the email.

I hope this is helpful.

Kind Regards,
Judy Fox

Judy Fox Simmons | Director of Compliance Services
QPharma, Inc. | 45 Horsehill Rd. | Cedar Knolls NJ 07927
610.212.0982 (Mobile)
judy.fox@qpharmacorp.com

Your Commercial and Compliance Partner

From: Judy Fox <Judy.Fox@qpharmacorp.com>
Sent: Tuesday, October 12, 2021 4:16 PM
To: Numi.L.Griffith@dcbs.oregon.gov
Cc: Judy Fox <Judy.Fox@qpharmacorp.com>
Subject: RE: Comments on Oregon Rep Licensing SB7630 - last email, I promise!

Hi Numi,

My apologies for the numerous emails, but I thought you might be interested in the response I received from the FDA regarding a value assigned to prescription drug samples.
As you may be aware, the FDA is responsible for the regulations and enforcement of the PDMA and that is where any violation of federal law on this topic would be found and enforced.

I posed this question to the Karen Rothschild, who previously had PDMA Compliance responsibilities at the FDA:

> Oregon is in the process of drafting the rules for a new law on such a topic where they require sales representative licensing as well as transparency reporting. In the report they ask for drug sampling information including the " monetary value of the samples" distributed to Oregon practitioners. During the public meeting

on the draft rule, a comment was made that if manufacturers were to assign a value to their samples, it would be a violation of federal law since samples cannot be sold. I could not find any relevant federal regulations that would prohibit a manufacturer from assigning a monetary value to their samples, especially if the value is used only for transparency reporting purposes.

My question to you is if Oregon were to require manufacturers to assign a dollar value to their samples based on either the cost to produce the samples or the cost of the equivalent in trade product, would there be any concerns for such a requirement on the part of the FDA?

This is the response I received from Karen:

I am not currently working on PDMA issues, as I am on a detail with FDA's Office of Generic Drug Policy. So I will *unofficially* opine to you that I do not see a problem with FDA compliance if a company were to assign an internal dollar value to a prescription drug sample. In fact, in my opinion, one of the things that inspired our increased oversight of PDMA drug sample distribution was in recognition that samples are items of value, and should be treated as such. I also think that a distinction can be made between the value of something, and the cost to consumers (in this case, zero).

I am copying the appropriate mailbox in the Office of Compliance so that this can make it to the appropriate people, who can let you know if the office has a different interpretation than I do.

I hope this is helpful.

Kind Regards,
Judy Fox

Judy Fox Simmons | Director of Compliance Services
QPharma, Inc. | 45 Horsehill Rd. | Cedar Knolls NJ 07927
610.212.0982 (Mobile)
judy.fox@qpharmacorp.com

Your Commercial and Compliance Partner

From: Judy Fox
Sent: Tuesday, October 12, 2021 2:43 PM
To: DFR.rules@oregon.gov.; Numi.L.Griffith@dcbs.oregon.gov
Cc: Keith Westrich <Keith.Westrich@qpharmacorp.com>; Judy Fox <Judy.Fox@qpharmacorp.com>
Subject: Comments on Oregon Rep Licensing SB7630

Good Afternoon Numi,

I hope this email finds you well. I am including you directly on this email because the DFR.rules@oregon.gov email address for comments is coming back as invalid.

QPharma is a consulting and warehousing vendor for the pharmaceutical industry. Attached to this email, please find our Comments on the draft rule of SB7630 that I am submitting as a result of meeting with several of our clients.

For some background on QPharma and our experience in this area, our services include assisting clients in managing sales representative licensing in Chicago and Washington DC and registrations in Nevada. This includes assisting in any transparency reporting required by federal and state regulations. As a CE provider in the industry, QPharma's course library has qualified us an approved provider of CE for both Chicago and Washington DC sales representative licensing. I

also worked with Kate McCabe, former Vermont Assistant Attorney General and provided insight into the Vermont rule for sample and spend reporting during its rule change

I am including Keith Westrich on this email. Keith is the Managing Director of our CE Programs here at QPharma and he would be happy to work with the state for the initial sales representative CE requirements as QPharma goes through the application process to be an approved CE provider for licensing renewal.

Please feel free to contact me or Keith if you have any questions about how we comply with the other states or would like some insight into our CE programs.

Kind Regards,

Judy Fox

Judy Fox Simmons | Director of Compliance Services
QPharma, Inc. | 45 Horsehill Rd. | Cedar Knolls NJ 07927
610.212.0982 (Mobile)
judy.fox@qpharmacorp.com

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