Sheinberg, Samuel I.

From: [Redacted]
Sent: Tuesday, May 28, 2019 10:51 AM
To: Walsh, Kathryn E.; Berg, Karen E.; Biagioli, Kimberley; Carson, Timothy; Sheinberg, Samuel I.; Six, Anne
Subject: FW: Question re: 802.1

From: [Redacted]
Sent: Tuesday, May 28, 2019 10:50:48 AM (UTC-05:00) Eastern Time (US & Canada)
To: [Redacted]
Cc: [Redacted]
Subject: RE: Question re: 802.1

The PNO recognizes PRVs as reportable assets not exempt under 802.1

From: [Redacted]
Sent: Saturday, May 25, 2019 5:03:15 PM (UTC-05:00) Eastern Time (US & Canada)
To: [Redacted]
Subject: Question re: 802.1

All,

I am writing to inquire about the applicability of 802.1 to the acquisition of a Priority Review Voucher (“PRV”). A PRV is awarded by the Food and Drug Administration to sponsors of rare pediatric or neglected tropical disease product applications that meet certain criteria. A sponsor who receives an approval for a drug or biologic of a rare pediatric or neglected tropical disease may qualify for a PRV that can be redeemed to receive a priority review of a subsequent marketing application for a different product.

PRVs are transferrable and may be sold to other pharmaceutical companies, which may use a PRV for priority review of its marketing application of a new product. I want to confirm whether the acquisition of a PRV by another pharmaceutical company to use in the ordinary course of its business, and not acquired in connection with any other assets (e.g., all commercially significant exclusive patent rights) or an acquisition of all or substantially all of the assets of an operating unit would be exempt under 802.1(c) as a current good to be used “for consumption in the acquiring person’s business.”

Please let me know if you have any questions or require additional information.