

## Sheinberg, Samuel I.

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**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

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**From:** Whitehead, Nora  
**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](#)

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**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.

[REDACTED]

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