ITEM 5

Verne, B. Michael

From: [redacted]
Sent: Thursday, May 01, 2014 11:02 AM
To: Walsh, Kathryn; Verne, B. Michael
Subject: Item 5(a) Questions

Kate / Mike:

I have a few questions about how to report in Item 5(a) for a pharmaceutical development company (hereinafter "Company A") that earns revenue from direct product sales as well as licenses.

NAICS Classifications

I realize that the PNO defers to the Census Bureau's interpretation of NAICS classifications. However, given that pharmaceutical licensing arrangements were the subject of a recent rule and an industry in which the PNO is very familiar, I wanted to make sure that we are classifying revenues consistently with the PNO's expectations.

Company A is a pharmaceutical company primarily focused on the research and development of new pharmaceutical products. NAICS 541711 – Research and Development in Biotechnology best represents the company as a whole but not the manner in which is generates revenues, which are by direct product sales or revenues generated from licensing and collaboration agreements with other pharmaceutical companies.

I want to confirm that you agree with our classification of revenues under the following NAICS codes:

- *325412 – Pharmaceutical Preparation Manufacturing (Note: would report under 10-digit code):* Any revenues from pharmaceutical product sales that Company A manufacturers.

- *424210 – Drugs and Druggists' Sundries Merchant Wholesalers:* Any revenues from pharmaceutical product sales that are manufactured by a third party but sold and distributed by Company A.

- *533110 – Lessors of Nonfinancial Intangible Assets (except Copyrighted Works):* Any revenues generated from an agreement pursuant to which Company A licensed to Company B exclusive rights to develop and commercialize a product, including (i) upfront payments, (ii) milestones, (iii) profit and loss sharing from co-promotion of the product, and (iv) product royalties.

I primarily want confirmation that the revenues generated pursuant to the licensing and collaboration agreement are appropriately classified under NAICS 533110, which applies to "establishments primarily engaged in assigning rights to assets, such as patents, trademarks, brand names, and/or franchise agreements for which a royalty payment or licensing fee is paid to the asset holder." If you do not agree, then what is the appropriate NAICS for these revenues?

Licensing Revenues for Products Sold Abroad

Company A also granted an exclusive license to Company C to develop and commercialize a product outside of the United States. Company A is incorporated and headquartered in the United States. Please confirm that we would report Company A's licensing revenues in Item 5(a) because these revenues were generated by a U.S. establishment and that they would not be excluded because the actual sales of the pharmaceutical products were made outside the U.S. by Company C, which we will assume is a non-U.S. company.

Revenue Recognition / Deferred Revenue

2

In its annual financial statements, Company A defers some of its payments under its licensing agreements. For example, Company A defers and recognizes upfront and milestone payments over a period of time. How should revenues be reported in Item 5(a): (i) consistent with Company A's revenue recognition methods or (ii) the year in which they are generated (e.g., record all of a milestone payment made in FY 2013 in Item 5(a)). I assume (ii) is the correct approach, but please confirm.

Please let me know if you have any questions.

Thank you,

[redacted]

[redacted]

1 NAICS CLASSIFICATIONS - AGREE ON ALL THREE
2 LICENSING REVENUES FOR PRODUCTS SOLD ABROAD - AGREE

3 REVENUE RECOGNITION - (ii) IS CORRECT.

BMW
5/1/14

KW CONCURS