Beaver, Nate

From:

Stewart, Kendra < Kendra. Stewart@fda.hhs.gov>

Sent:

Thursday, October 12, 2017 10:54 AM

To:

Beaver, Nate

Subject:

RE: Orange Book Listing Date

Dear Nathan Beaver,

Per Orange Book records, the '507 patent was listed on the Orange Book website on 5/19/2016 and the '240 patent was listed on 6/9/2016.

Regards,

CAPT Kendra S. Stewart, R.Ph., Pharm.D. **US Public Health Service** Supervisor, Orange Book Staff

Center for Drug Evaluation and Research Office of Generic Drugs U.S. Food and Drug Administration Tel: 240-402-8797

ORANGE BOOK QUESTIONS: OrangeBook@fda.hhs.gov

WEBSITE: www.fda.gov/orangebook











From: NBeaver@foley.com [mailto:NBeaver@foley.com]

Sent: Wednesday, October 11, 2017 4:26 PM

To: Stewart, Kendra

Subject: Orange Book Listing Date

Dr. Stewart.

This follows up on a voicemail I left you earlier today. We represent United Therapeutics (UT) and are trying to confirm the date of publication in the Orange Book (i.e., the date the electronic OB was updated and patent information was publicly available) for two US Patents that were submitted by UT:

US Patent Nos. 9,339,507 and 9,358,240

These were submitted for listing by UT on 6/8/2016 for Tyvaso with respect to the '240 patent and on 5/17/2016 with respect to the '507 patent .

I am hoping that Orange Book Staff can confirm this information and respond by email with the actual date of listing in the OB.

Thank you.





Best regards,

Nate

Nathan A. Beaver, Partner Foley & Lardner LLP – 3000 K St. NW, Suite 600 Washington, DC 20007 (p) 202-295-4039 – (f) 202-672-5399 nbeaver@foley.com

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